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June 13, 2000

BY HAND DELIVERY

Dockets Management Branch
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20857

Re: Docket No. 00P-0499/CP 1

The undersigned, on behalf of SmithKline Beecham Corporation ("SmithKline"), submits this response to the above-captioned February 3, 2000, citizen petition filed on behalf of Apotex, Inc., the TorPharm Division of Apotex, Inc., and Apotex Corporation (collectively, "Apotex"). In that petition, Apotex requests that FDA delist two of the patents listed in the Orange Book in connection with SmithKline's NDA No. 20031, United States Patent Nos. 5,900,423 ("the '423 patent") and 5,872,132 ("the '132 patent"). Apotex further requests that the Commissioner refuse to permit any activity with respect to the two SmithKline patents or any patent issued to SmithKline in the future that would delay FDA's review and approval of Apotex's ANDA No. 075-356. This response supplements the preliminary response submitted by SmithKline on February 29, 2000.

The petition should be denied for the following reasons. *First*, the regulations are clear that FDA will not involve itself substantively in patent disputes of the nature that Apotex presents in its citizen petition and will instead defer to the patent holder with respect to listing questions. FDA would violate its own regulations and the Federal Food, Drug, and Cosmetic Act ("the Act") if it were to grant the relief requested by Apotex. *Second*, the listing issue already is before the federal court hearing the infringement cases brought by SmithKline on these patents, and FDA should allow the question to be decided there. *Third*, if FDA were to reach the merits, it should rule that the patents were properly listed in accordance with the statutory language and policy, consistent with congressional intent and the only court case to address the precise question presented. *Fourth*, denial of the citizen petition is consistent with FDA's position in the litigation brought by Apotex against the agency and with the court's denial of Apotex's motion for a preliminary injunction.

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1. The Act and FDA's regulation preclude the agency from either refusing to list or delisting a patent submitted by an NDA holder.

Subsections (b)(1) and (c)(2) of section 505 of the Act (21 U.S.C. § 355(b)(1) and (c)(2)) provide that FDA "shall" publish patent information submitted by the holder of an approved NDA. The legislative history of these provisions fully reinforces the plain language Congress used to state its intent: "*The FDA is required to publish* the patent information upon its submission."[1] The corresponding regulation, 21 C.F.R. § 314.53, reflects FDA's policy of not getting involved in patent listing disputes. That section provides that if patent listing information is disputed, the person questioning "the accuracy or relevance of patent information . . . must first notify the agency in writing stating the grounds for disagreement."[2] 21 C.F.R. § 314.53(f). FDA then will contact the NDA holder and request confirmation of the correctness of the patent information. Unless the NDA applicant amends or withdraws listing information, however, FDA is prohibited from changing the listed patent information. *Id.* As the agency explained in promulgating the regulation, "[d]isputes between ANDA applicants and patent holders regarding the validity or correctness of the listed patent information must be resolved among the ANDA applicants and the patent holders rather than by agency action."[3]

FDA therefore is prohibited from second-guessing the correctness of a patent listing decision, and for good reason. For at least twenty years, FDA has consistently disclaimed having the expertise or resources needed to resolve patent disputes.[4] The interpretation of patent claims is an issue of law to be decided by the courts.[5] Such interpretation can involve not only a review of the prosecution history of the patent but "extrinsic evidence," as well, including treatises, dictionaries, articles and the testimony of the inventors and of experts.[6] Clearly, such reviews can consume significant time and resources on the part of the reviewing body. Moreover, the law regarding how to interpret certain kinds of claims may not be clear or may be in flux. As a result of considerations such as these, Congress established a generic drug approval process

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[1] H.R. Rep. No. 857, 98th Cong., 2d Sess., Part 2, at 18 (1984) (emphasis added).

[2] Apotex did not to our knowledge follow this required procedure before submitting its citizen petition.

[3] 59 Fed. Reg. 50338, 50348 (Oct. 3, 1994).

[4] *See, e.g.*, 45 Fed. Reg. 72582, 72598 (Oct. 31, 1980); 54 Fed. Reg. 28872, 28909 (July 10, 1989) ("FDA has no expertise in the field of patents"); 59 Fed. Reg. at 50345 ("FDA does not have the resources or the expertise to review patent information for its accuracy or relevance").

[5] *Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996).

[6] *Markman*, 52 F.3d at 980.

under which FDA has a ministerial, mandatory duty to publish patent information without getting substantively involved in interpreting patents or otherwise assessing the accuracy of the information. Congress specifically assigned the often onerous task of interpreting patent claims to the courts.

Apotex argues that "Congress required FDA to supervise patent filings," and that FDA may not "rely on private causes of action between ANDA applicants and NDA applicants to police the accuracy of patent listings in the Orange Book." Cit. Pet. 16 and 17. In support of this position, Apotex cites 21 U.S.C. § 355(e)(4), which allows FDA to withdraw the approval of an NDA if the agency finds that the required patent information was not filed within 30 days of receipt by the NDA holder of written notification from the Secretary of the failure to file. This statutory provision in no way supports Apotex's assertion that FDA must police the accuracy of patent listings and refuse to list or delist patents. On the contrary, the provision states merely that if FDA learns that patent information should have been, but was not, submitted for listing, FDA may so notify the NDA holder and may withdraw approval if the NDA holder still does not file the information.

The statutory scheme established by Congress instead mandates that disputes regarding the coverage of patent claims must be decided in the courts, and not by FDA. Patent litigation involves some of the most complex and technology-intensive legal disputes imaginable. FDA has neither the resources nor the expertise to determine patent coverage issues for every listed patent.[7] The patent listing, certification and 30-month stay provisions were all intended to give NDA holders and ANDA applicants procedures by which to resolve patent-related disputes. The fact that Congress selected a 30-month period is indicative of the recognition that patent disputes can be extremely complex and time-consuming, particularly in the pharmaceutical area.

Apotex thus cannot succeed by attacking FDA's regulations as inconsistent with congressional intent, because, as explained above, both use virtually identical mandatory language. At a bare minimum, the regulations easily satisfy the *Chevron* test.[8] Nor is there any improper "delegation" under the regulations to private parties. The regulations carry forward exactly the policy adopted by Congress, which is to keep FDA out of patent disputes.[9] FDA

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[7] In support of its argument that FDA has the resources to decide patent issues, Apotex asserts that fewer than thirty patents were submitted for Orange Book listing in 1999. SmithKline submits that if FDA were forced to consider the kinds and volume of evidence reviewed by courts in determining patent claim coverage for every one of these patents, the agency's legal resources could be so taxed that they would have time to do little else.

[8] *Chevron U.S.A.* v. *NRDC*, 467 U.S. 837 (1984).

[9] Any suggestion that the statute itself is unconstitutional under the delegation doctrine would be utterly implausible. Private parties are not given the right to make any final determination that (continued...)

acted properly by publishing the information submitted to it by SmithKline. The regulations preclude the agency from granting the relief requested in the citizen petition.

2. FDA should not interfere with the patent court's consideration of the listing issue.

As Apotex acknowledged in its citizen petition, SmithKline brought a patent infringement action against Apotex in the United States District Court for the Eastern District of Pennsylvania following its receipt of Apotex's notice of a paragraph IV certification regarding the '423 patent.[10] In that notice, dated July 12, 1999, Apotex asserted that there was then a live and justiciable controversy over SB's submission of the '423 patent to FDA for listing in the Orange Book.[11] Thus, Apotex admitted then what it attempts to deny now – that its dispute over the listing issue should be resolved in litigation with SmithKline, not by dragging FDA into the fray. Inexplicably, however, Apotex failed to challenge the patent listing in the Philadelphia litigation, where that issue belongs. The patent case already is underway there, and the effect of the patent listing is directly felt there: it gives rise to a 30-month stay of approval of the ANDA under 21 U.S.C. § 355(j)(5)(B)(iii).

In fact, the two other ANDA applicants sued by SmithKline in Philadelphia for infringement of the '423 patent have raised the listing question there. Geneva raised it by counterclaim almost a year ago, on July 29, 1999.[12] Zenith, which was sued only this past March, raised it as well, on April 13, 2000.[13] Those cases were assigned as related cases to the same judge hearing the case against Apotex, and a motion for consolidation of all three currently is pending.

Issues relating to interpretation and listing of the '423 patent are subject to the Philadelphia court's jurisdiction and should be resolved there, rather than by FDA. In the agency's own words, "[d]isputes between ANDA applicants and patent holders regarding the validity or correctness of the listed patent information must be resolved among the ANDA

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could rest only with the government; rather they simply are provided with the opportunity, in the first instance, to submit their patents for listing, subject to a court's ruling later than the listing was improper or that the patents are invalid or not infringed.

[10] *SmithKline Beecham Corp.* v. *Apotex Corp. et al.*, Civ. No. 99-4304 (E.D. Pa.) (Kauffman, J.).

[11] The paragraph IV notice appears as exhibit L to Apotex's complaint in its action against FDA.

[12] *SmithKline Beecham Corp. et al.* v. *Geneva Pharmaceuticals, Inc.*, Civ. No. 99-2926 (E.D. Pa.) (Kauffman, J.).

[13] *SmithKline Beecham Corp. et al.* v. *Zenith Goldline Pharmaceuticals, Inc.*, Civ. No. 00-1393 (Kauffman, J.).

applicants and the patent holders rather than by agency action."[14] Apotex first recognized in its paragraph IV notice of July 12, 1999, that its dispute really is with SmithKline.[15] Apotex has since done everything it can to avoid resolving that dispute and instead reframe its complaint as one against FDA. Notwithstanding these maneuvers, the Philadelphia court is the logical forum to decide the dispute. The issue already is pending there, and that is the court before which patent infringement evidence will be fully developed and adjudicated. Under the congressionally designed statutory scheme and the applicable regulations, the Philadelphia court – and not FDA – is the proper forum.

3. The patents are properly listed.

Under the Act and FDA regulations, the agency is not permitted to reach the question of whether the '423 and '132 patents satisfy the criteria for listing in the Orange Book. In the event that FDA does decide to review this issue, however, we briefly set forth the reasons why the patent listings are correct: the active ingredient is paroxetine hydrochloride, and these patents claim paroxetine hydrochloride; the hemihydrate and anhydrous forms of paroxetine hydrochloride are considered by FDA and asserted by Apotex to be the same; and the relevant court cases support listing.

The statute provides in relevant part that patent information must be submitted for "any patent which claims the drug for which the application was submitted."[16] The term "drug" as used in the statute and regulations includes active ingredients, finished dosage forms (such as capsules or tablets), and any "component" of a drug, whether or not it is present in the finished dosage form.[17] The regulations further provide that a drug substance (active ingredient) patent, such as the '423 and '132 patents, must be listed if it claims a component of an approved drug product.[18]

The active ingredient of Paxil (the approved drug product) is paroxetine hydrochloride. A simple review of the FDA-approved labeling for the drug will confirm this. This also is the active ingredient of the approved product as set forth in the Orange Book listings of approved

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[14] 59 Fed. Reg. 50338, 50348 (Oct. 3, 1994).

[15] It stated in its notice as follows (page 5): "TorPharm hereby notifies SmithKline that it is TorPharm's position that the '423 patent was not properly listed by SmithKline with the FDA. Accordingly, there presently exists a justiciable controvery over whether the '423 patent was properly listed."

[16] 21 U.S.C. § 355(c)(2).

[17] *See* 21 U.S.C. § 321(g)(1); 21 C.F.R. § 210.3(b).

[18] 21 C.F.R. § 314.53(b).

drug products and of patent and exclusivity information.[19] The '423 and '132 patents claim paroxetine hydrochloride and thus claim the "drug" under the statute and regulations.[20]

To be sure, paroxetine hydrochloride is present in Paxil in a particular polymorphic or crystalline form known as a "hemihydrate," while the patents cover different forms known as the "anhydrous" forms A and C. The active ingredient as approved by FDA and listed in the Orange Book, however, is simply paroxetine hydrochloride. Thus, the patent claims the drug substance as defined by FDA and is eligible for listing.

The Orange Book provides, moreover, that "[a]nhydrous and hydrated entities, as well as different polymorphs, are considered pharmaceutical equivalents."[21] This means that FDA, in its discretion, considers them to be the same active ingredient: "Drug products are considered pharmaceutical equivalents if they contain the same active ingredient(s) . . . ."[22]

Indeed, Apotex has asserted that the hemihydrate and anhydrous forms are the same active ingredient, because that is the entire basis for its ANDA. To be considered under the ANDA process, Apotex's product must use the "same" active ingredient as Paxil (under the regulations, this means the "identical" active ingredient).[23] It is inconceivable that Congress meant to allow a company such as Apotex to assert that it is using the same active ingredient for ANDA approval purposes while denying SmithKline the right to list patents for the same active ingredient. Such a result would give Apotex the right to piggyback on SmithKline's data while denying SmithKline the right to enforce its patents prior to marketing of the generic product. This would be directly contrary to the balance struck by Congress in the Hatch-Waxman Amendments. In other words, if the hemihydrate and anhydrate are the same drug for ANDA approval purposes, they must be considered the same drug for patent listing purposes as well. Indeed, if Apotex were to prevail on its argument that the hemihydrate and anhydrous forms are different active ingredients, then its ANDA was not properly filed, and it should be ordered to withdraw the application.

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[19] *See* Orange Book (20th ed. 2000), at 3-262 and ADA41.

[20] If the regulations were interpreted to preclude listing under these circumstances, they would be invalid because they would restrict the universe of eligible patents more narrowly than Congress intended through its use of the broad statutory term "drug."

[21] Orange Book, *supra*, at xv.

[22] *Id.* at vii. *See also* 57 Fed. Reg. 17950, 17959 (April 28, 1992) (FDA generally considers different crystalline forms to be the same but may prescribe additional standards on a case-by-case basis).

[23] 21 C.F.R. § 314.92(a)(1).

The case law supports SmithKline on the appropriateness of listing the patents here. In *Ben Venue Laboratories, Inc. v. Novartis Pharmaceutical Corp.*,[24] the district court held that a patent on one crystalline form of an active ingredient was properly listed even though it did not appear in the finished dosage form. The court there also cited the unpublished decision in *Zenith Laboratories, Inc.* v. *Abbott Laboratories*, Civ. No. 96-1661 (D.N.J. Oct. 1, 1997), a copy of which was provided as Exhibit J to the citizen petition, in which the district court squarely held that a patent on an anhydrous form of a drug was properly listed even though the approved product used a hydrated form (exactly the situation here).[25] The *Ben Venue* court also distinguished the case cited by Apotex at page 16 of its citizen petition, *Pfizer* v. *FDA*.[26] That case concerned a patent for an unapproved dosage form considered by FDA to be different from the approved dosage form (tablet vs. capsule), not a patent on the active ingredient considered to be the same.[27] FDA distinguished the *Pfizer* decision on the same basis in the case brought by Apotex against the agency (see section 4, *infra*).

The declarations SmithKline submitted to list the patents were proper under both the statute and regulations. As explained above, 21 U.S.C. § 355(c)(2) requires that patent information be submitted for "any patent which claims the drug for which the application was submitted." The declarations on their face state everything that is required to be stated by the regulations and thus must be accepted by the agency. The fact that they go on to provide in very summary fashion a further explanation of the basis for the listing – in the interest of forestalling any assertion by Apotex or other ANDA applicants of improper conduct – hardly makes them defective.

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[24] 10 F. Supp. 2d 446 (D.N.J. 1998).

[25] Apotex spent a great deal of time in its citizen petition attempting to distinguish the *Zenith* case. The holding, however, is well-reasoned and directly on point. The *Zenith* court relied on FDA's own language in the preamble to the Orange Book regarding the equivalence of anhydrous and hydrated entities, as cited above, to determine what patents should be listed therein. The *Zenith* court also quoted a CDER letter as indicating that FDA considers "differences in waters of hydration resulting in polymorphic crystal forms of the same active moiety (i.e., different forms of the same active ingredient) to be the same when dissolution, solubility, and absorption are shown to be equivalent." *Zenith* slip op. at 24. The *Zenith* court concluded that the equivalence of the dissolution, solubility, and absorption of the hydrated and anhydrous forms at issue in that case raised an issue of fact to be determined at trial.

[26] 753 F. Supp. 171 (D. Md. 1990).

[27] *See* 10 F. Supp. 2d at 454-455.

In short, SmithKline properly listed the patents. There is a clear basis for the listing, and FDA cannot conceivably have abdicated any statutory responsibility in accepting them for publication. SmithKline acted in accordance with its statutory duty to list the patents[28] and in accordance with Congress's intent to identify and resolve patent disputes prior to ANDA approval. If Apotex wishes to pursue this issue further, it should take it up with the judge in Philadelphia rather than drawing FDA into what is, under the statute and regulations, a dispute between private parties.

Apotex makes one final argument against listing: that a patent issued after NDA approval can be listed only if no patents were listable at the time the NDA was approved. This argument has no support in the statute and makes no sense as a policy matter. Subsection (b) of the relevant statutory provision requires the listing with the NDA of "any patent" meeting eligibility criteria.[29] The law further specifies that if "the patent information described in subsection (b)" could not be filed with the NDA because "a patent was issued after the application was approved," then it must be filed within 30 days of patent issuance.[30] Nothing suggests that the second provision applies only if *no* patent originally was listable with the NDA. To the contrary, the reference to "any patent" in the first subsection naturally suggests that "any patent" must be listed under the second as well. Apotex cannot point to any basis for overturning FDA's rule, particular in view of the deference to which the agency is entitled under *Chevron* on this point. There is no evidence that Congress intended to exclude from listing patents granted after NDA approval, and such an approach would discourage further research and innovation relating to approved drugs.

This result makes perfect sense as a policy matter as well. There is no reason why an NDA holder's right to invoke the patent listing, lawsuit, and 30-month stay protections should depend on the vagaries of whether a particular patent was or was not issued at the time of NDA approval. FDA's regulations deal with the potential for abuse by providing that an NDA holder that fails to file a patent within 30 days of issuance loses the right to invoke the 30-month stay against pending ANDA applicants.[31]

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[28] If a patent qualifies for listing, the NDA holder must list it, and, as Apotex points out, the NDA can even be withdrawn for failure to list. *See* 21 U.S.C. § 355(b)(1), (c)(2), and (e)(4).

[29] 21 U.S.C. § 355(b)(1).

[30] 21 U.S.C. § 355(c)(2).

[31] *See* 21 C.F.R. § 314.94(a)(12)(vi).

4. Denial of the citizen petition is consistent with FDA's position and the court's decision in the litigation brought by Apotex against the agency.

Apotex raises many of the same arguments in its citizen petition that it raised in the United States District Court for the District of Columbia in *Apotex, Inc. v. Shalala*, Civil Action No. 1:00CV00729. In that case, Apotex brought suit against FDA seeking a preliminary injunction and final order requiring FDA, among other things, to delist the '423 patent and the '132 patent and to continue the process of considering Apotex's ANDA without regard to these patents, and prohibiting FDA from listing any additional patents in connection with SmithKline's NDA.[32] FDA's arguments in that case support SmithKline's position here. The motion to dismiss and reply brief filed in that case on behalf of FDA are attached as Exhibits 1 and 2. FDA's decision on this citizen petition should be consistent with the position FDA took in the federal court. SmithKline also attaches the decision of the district court denying Apotex's motion for a preliminary injunction and the transcript of the hearing on the motion as Exhibits 3 and 4.

Conclusion

For the foregoing reasons, the citizen petition is without merit and should be denied.

Respectfully submitted,

Bruce Kuhlik

Bruce N. Kuhlik

Counsel for SmithKline Beecham Corp.

cc: Hugh J. Moore, Esq.
Lord, Bissell & Brook

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[32] As Apotex has advised FDA, SmithKline is developing other patents and new innovations regarding paroxetine hydrochloride for which patent protection, where appropriate, has been or will be sought. SmithKline will evaluate such patents as they are issued by the United States Patent and Trademark Office, and will list the patents as and where required. Information on one patent was submitted to FDA earlier this week. Where SmithKline is not required to list a particular patent, it will not do so. Moreover, the fact that a patent is listed as required does not mean that it will be asserted against any particular ANDA applicant. For example, SmithKline did not sue Apotex on the '132 patent.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

APOTEX, INC.,
Plaintiff,

v.

DONNA E. SHALALA, et al.,
Defendants.

Civ. No. 1:00CV00729 (TPJ)

MOTION TO DISMISS

Pursuant to Federal Rule of Civil Procedure 12(b)(1) and 12(b)(6), the defendants hereby move to dismiss this action. The grounds for this motion are set forth fully in the memorandum of points and authorities filed simultaneously herewith.

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April 12, 2000.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

APOTEX, INC., Plaintiff,	
v.	Civ. No. 1:00CV00729 (TPJ)
DONNA E. SHALALA, et al., Defendants.	

DEFENDANTS' MEMORANDUM IN OPPOSITION
TO PLAINTIFF'S APPLICATION FOR PRELIMINARY
INJUNCTION AND IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

INTRODUCTION

Apotex, Inc., challenges the listing by the Food and Drug Administration (FDA) of two patents for Paxil®, a drug manufactured by SmithKline Beecham (SmithKline) that is used for the treatment of depression. Apotex seeks to market a generic version of Paxil®. However, because the two additional patents have been listed for Paxil® while Apotex's abbreviated new drug application (ANDA) is pending, Apotex was required by the Food, Drug, and Cosmetic Act (FDCA) to certify to those two new patents. Apotex did so, and SmithKline promptly sued Apotex for patent infringement. Because SmithKline filed its patent infringement suit within 45 days of receiving Apotex's patent certifications, SmithKline receives the benefit of a 30-month statutory stay during which Apotex's ANDA may not be approved. *See* 21 U.S.C. § 355(j)(5)(B)(iii). Nonetheless, Apotex has moved this Court to enter a preliminary injunction. For several

reasons, this motion should be denied an Apotex's complaint dismissed.

First, this case is not ripe because Apotex's ANDA cannot by law be approved prior to November, 2000, and thus Apotex cannot suffer its alleged injury until that time. Second, Apotex has failed to exhaust administrative remedies, and its complaint can also be dismissed for that reason. Finally, should the Court reach the substance of Apotex's motion for preliminary injunction, the motion should be denied. In particular, Apotex has failed to demonstrate a likelihood of success on the merits because the "injury" of which it complains is compelled by statute. Also, Apotex has not shown that it will suffer imminent injury because, as stated above, its ANDA is not eligible for approval before November 2000.

STATUTORY AND REGULATORY FRAMEWORK

At issue in this case are provisions of the FDCA and implementing regulations that apply to new drug applications and to generic drug approvals. 21 U.S.C. § 355; 21 C.F.R. § 314.53. The statutory provisions were added to the FDCA through the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Amendments. Pub. L. No. 98-417, 98 Stat. 1585 (1984). Title I of the Hatch-Waxman Amendments was intended "to make available more low cost generic drugs by establishing a generic drug approval procedure for

pioneer drugs first approved after 1962." H.R. Rep. No. 857 (Part I), 98th Cong., 2d Sess. at 14 (1984), reprinted in 1984 U.S.C.C.A.N. 2647. Title II of the Hatch-Waxman Amendments was intended to provide a new incentive for increased expenditures for research and development of pioneer drug products by "restoration of some of the time lost on patent life while the product is awaiting pre-market approval." H.R. Rep. No. 857 (Part I), 98th Cong., 2d Sess. at 15 (1984), reprinted in 1984 U.S.C.C.A.N. at 2648. The statutory scheme crafted by Congress represents a balancing of these two policy goals.

I. New Drug Applications

Under the FDCA, pharmaceutical companies seeking to market pioneer or innovator drugs must first obtain FDA approval by filing a new drug application (NDA). 21 U.S.C. § 355(a), (b). In addition to submitting data demonstrating the safety and effectiveness of the drug, an NDA applicant, also referred to as a sponsor, is required to submit information on any patent that claims the drug or a method of using the drug for which a claim of patent infringement could reasonably be asserted against an unauthorized party. 21 U.S.C. § 355(b)(1), (c)(2). The patent information must include the patent number and date of expiration. *Id.* For patents covering the formulation, composition, or method of using a drug, the NDA applicant must submit a signed declaration stating that the patent covers the

formulation, composition, or use of the product described in the application. 21 C.F.R. § 314.53(c)(2). If a patent is issued after an NDA is approved, the required patent information shall be submitted to FDA within 30 days of the issuance of the patent. 21 C.F.R. 314.53(d)(3).

FDA is required to publish patent information, and does so in Approved Drug Products With Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book." When publishing patent information related to an NDA, FDA acts in a ministerial capacity, relying on the applicant's assessment of the applicability of the patent to the drug without making an independent determination of the merits or applicability of patent claims. 59 Fed. Reg. 50338 at 50342-43, 50345, 50349, 50352 (October 3, 1994) (preamble to final rule implementing patent and exclusivity provisions of the Hatch-Waxman Amendments). In the event of a dispute as to whether a particular patent has been properly listed in the Orange Book, FDA must be notified in writing of the grounds for the dispute. 21 C.F.R. § 314.53(f). FDA will then request the NDA holder to confirm the correctness of the patent information. *Id.* Unless the NDA holder withdraws or amends its patent information, FDA will not change the patent information in the Orange Book. *Id.* The statutory scheme relies on private patent litigation to

resolve disputes concerning patent validity and applicability. 59 Fed. Reg. at 50345, 50348.

II. Abbreviated New Drug Applications

The Hatch-Waxman Amendments permit the submission of abbreviated new drug applications (ANDAs) for generic versions of drugs. 21 U.S.C. § 355(j). Under the abbreviated procedure, ANDA applicants may rely upon FDA findings of safety and effectiveness for the pioneer drug product. 21 U.S.C. § 355(j)(2). The statute requires that an ANDA contain, among other data and information, a certification with respect to each patent that claims the drug or the method of the drug's use for which patent information is required to be filed. 21 U.S.C. § 355(j)(2)(A)(vii). This certification must state one of the following:

(I) that the required patent information relating to such patent has not been filed;

(II) that such patent has expired;

(III) that the patent will expire on a particular date; or

(IV) that such patent is invalid or will not be infringed by the drug for which approval is being sought.

If a certification is made under paragraph I or II indicating that patent information pertaining to the drug or its use has not been filed with FDA or the patent has expired, approval of the ANDA may be made effective immediately. 21 U.S.C. § 355(j)(5)(B)(i). A certification under paragraph III

indicates that the ANDA applicant does not intend to market the drug until after the expiration date of the applicable patent, and approval of the ANDA may be made effective on such expiration date. 21 U.S.C. § 355(j)(5)(B)(ii).

A paragraph IV certification – the paragraph at issue in this case – requires that the ANDA applicant give notice of the filing of the ANDA to the patent owner and the NDA holder for the listed drug, which notice must include a detailed statement of the factual and legal basis for the ANDA applicant's opinion that the patent is not valid or will not be infringed. 21 U.S.C. § 355(j)(2)(B). An applicant whose ANDA is pending when additional patents are listed must certify to the new patents, unless the additional patents are submitted more than 30 days after they are issued. 21 C.F.R. § 314.94(a)(12)(vi).

FDA may approve an ANDA with a paragraph IV certification, and the approval may become effective immediately, despite the unexpired patent, unless an action for infringement of the patent is brought against the ANDA applicant within 45 days of the date the patent owner and NDA holder receive notice of the paragraph IV certification. 21 U.S.C. § 355(j)(5)(B)(iii); 21 C.F.R. § 314.107(f)(2). If a patent action is brought, approval of the ANDA will not become effective until at least 30 months from the date that the patent owner and NDA holder received notice, unless a final decision is reached earlier in the patent case or the

patent court otherwise orders a longer or shorter period. 21 U.S.C. § 355(j)(5)(B)(iii)(I).

III. 180-Day Period of Market Exclusivity

As an incentive and reward to the first generic drug manufacturer to expose itself to costly patent litigation, the statute provides that the first manufacturer who files an ANDA containing a paragraph IV certification is eligible for a 180-day period of marketing exclusivity. 21 U.S.C. § 355(j)(5)(B)(iv); *see Mova Pharmaceutical Corp. v. Shalala*, 140 F.3d 1060, 1064 (D.C. Cir. 1998). The exclusivity can be triggered by either the first commercial marketing of the generic drug or by a decision of a court finding a patent covering the innovator drug invalid, unenforceable, or not infringed. 21 U.S.C. § 355(j)(5)(B)(iv).

FACTUAL BACKGROUND AND ADMINISTRATIVE PROCEEDINGS

Paxil® was approved by FDA in 1992. Apotex Compl. ¶ 19. In its NDA for Paxil®, SmithKline included information on patent 4,721,723 ('723). Upon approval, patent '723 was listed in the Orange Book for Paxil®. *Id.* at ¶ 21.

Apotex submitted an ANDA for generic Paxil® on March 31, 1998. *Id.* at ¶ 29. Apotex filed a paragraph IV certification to patent '723, and was sued by SmithKline for patent infringement within 45 days. *Id.* at ¶¶ 31, 35, 37. Because SmithKline filed suit within the 45-day time period provided by statute, it received the benefit of a 30-month stay of approval, which

expires November 21, 2000. *Id.* at ¶ 38; 21 U.S.C. § 355(j)(5)(B)(iii). Thus, Apotex's ANDA has not yet been approved, and cannot be approved until November, 2000. 21 U.S.C. § 355(j)(5)(B)(iii).

In February 1999, SmithKline was issued patent 5,872,132 ('132). Apotex Compl., ¶ 40. Within 30 days of the issuance of the patent, SmithKline filed information on patent '132 with FDA. In May 1999, SmithKline was issued patent 5,900,423 ('423). *Id.* at ¶ 43. Again, SmithKline submitted information to FDA on patent '423 within 30 days of its issuance. As required by 21 U.S.C. § 355(c)(2), FDA duly listed patents '132 and '423 in the Orange Book.

Apotex then submitted paragraph IV certifications for patents '132 and '423. *Id.* at ¶ 54. On August 9, 1999, Apotex was sued by SmithKline for patent infringement relating to the '423 patent. Litigation in the United States District Court for the Eastern District of Pennsylvania is pending. *See* Apotex Compl., Exh. M.

FDA's regulations require the filing of an administrative petition prior to the institution of a lawsuit complaining of agency action or inaction. 21 C.F.R. § 10.45(b). FDA is to respond to petitions within 180 days of receipt. 21 C.F.R. § 10.30(e)(2). On February 3, 2000, Apotex filed a citizen petition with FDA, seeking essentially the same relief it seeks

in this lawsuit. Apotex Compl., Exh. N. Apotex requested that FDA respond to its petition in 26 days, by February 29, 2000. Before receiving a response from FDA, Apotex filed this action on April 5, 2000.

ARGUMENT

I. THERE IS NO RIPE CASE OR CONTROVERSY BEFORE THIS COURT

As discussed above, Apotex's ANDA cannot be approved until November 21, 2000, because of the statutory 30-month stay following the initiation of SmithKline's 1998 lawsuit against Apotex. Apotex does not challenge this 30-month stay period. The injury that Apotex does allege results from the second 30-month stay following SmithKline's listing of patent '423 in 1999. This second 30-month period expires on January 15, 2002. However, this second 30-month period cannot even begin to cause Apotex's alleged injury until November 2000, when the first (unchallenged) 30-month period expires. Significantly, this second 30-month period can be shortened by the court hearing the patent case. 21 U.S.C. § 355(j)(5)(B)(iii). Apotex argues that it is absurdly obvious that the '423 patent cannot even remotely apply to SmithKline's Paxil product. Apotex App. at 20-24. If that is the case, Apotex will no doubt move to expedite the patent litigation, by a motion to dismiss or otherwise, and it is possible that the patent litigation on the '423 patent will be resolved before the unchallenged 30-month period expires in

November 2000. It is also be possible that the judge hearing the '423 patent litigation could shorten the second 30-month period.

Because of these contingent events, Apotex's claim is not ripe. "A claim is not ripe for adjudication if its rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." *Texas v. United States*, 523 U.S. 296, 300 (1998); *Pfizer Inc. v. Shalala*, 182 F.3d 975, 978 (D.C. Cir. 1999).

In order for a ripe controversy to exist, there must not only be final agency action, its effects must be "felt in a concrete way by the challenging parties." *Abbott Laboratories v. Gardner*, 387 U.S. 136, 148 (1967). In the instant case Apotex is suffering no "concrete" injury as a result of the listing of patents '132 and '423 (it has not even been sued with respect to patent '132).

It is possible that Apotex's ANDA approval will not be delayed beyond Nov 21, 2000, a delay that it does not challenge. Nor can Apotex assert that its patent litigation expense is a sufficient Article III case or controversy. *See FTC v. Standard Oil Co.*, 449 U.S. 232 (1980) (litigation expense – which was incurred there as a result of a "definitive" agency decision – is not sufficient to warrant the invocation of the judicial power of the United States courts); *Pfizer Inc.*, 182 F.3d at 979.

The statutory scheme contemplates that Apotex will have to litigate its patent disputes with SmithKline, and not with FDA. 21 U.S.C. § 355(j)(5)(B)(iii). Hence, Apotex's litigation expense cannot, as a matter of law, be viewed as an injury.

II. Apotex Failed To Exhaust Its Administrative Remedies

Apotex seeks review of FDA's action in this case under the Administrative Procedure Act (APA). Compl. ¶ 5. Yet, the APA requires that a party seeking relief from agency action exhaust administrative remedies if so required by agency regulation. 5 U.S.C. § 704; *DSE, Inc. v. United States*, 169 F.3d 21, 25 (D.C. Cir. 1999). FDA's regulation clearly requires that "[a] request that the Commissioner take or refrain from taking any form of administrative action must first be the subject of a final administrative decision based on a petition ... before any legal action is filed in a court complaining of the action or failure to act." 21 C.F.R. § 10.45(b). The regulation continues: "If a court action is filed complaining of the action or failure to act before the submission of the decision on a petition ... , the Commissioner shall request dismissal of the court action ... on the grounds of a failure to exhaust administrative remedies ...." *Id.*

Apotex has known of its alleged injury since FDA listed patents '132 and '423 in early 1999. Affidavit of Dr. David

Coffin-Beach ¶ 19. Indeed, Apotex was sued by SmithKline for infringing patent '423 on August 9, 1999. Furthermore, as a result of its patent litigation with SmithKline relating to patent '723, the listing of which Apotex does not contest, Apotex is not eligible for approval until November 2000.

Despite these facts, Apotex did not file an administrative petition with FDA until February 3, 2000, almost a year after the offending patents were listed by FDA and six months after Apotex was sued by SmithKline for infringing those patents.[2] Even though Apotex cannot be approved before November 2000, Apotex requested that FDA respond to its petition in just 26 days, by February 29, 2000. If FDA were given its full 180 days to respond to Apotex's petition, its response would be due August 3, 2000, five months before Apotex could even begin to suffer its alleged harm.

Apotex has not, and cannot, put forth any legitimate reason for not exhausting its administrative remedies as required by the APA and 21 C.F.R. § 10.45. Because FDA has not yet responded to Apotex's petition and the agency's time for response has not yet expired, this case is premature. 5 U.S.C. § 704; 21 C.F.R.

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[2] Recently Judge Roberts of this Court ruled that a delay in bringing suit contributed to the determination that the plaintiff would not suffer irreparable harm if a preliminary injunction was not granted. *Mylan Pharmaceuticals, Inc. v. Shalala*, 81 F. Supp.2d 30, 44 (D.D.C. 2000) (*Mylan I*). As discussed below, defendants believe, should the Court reach the merits of plaintiff's motion, the same result should obtain in this case.

§ 10.45(b); *Meyers v. Bethlehem Shipbuilding Corp.*, 303 U.S. 41, 50-51 (1938); *DSE v. United States*, 169 F.3d at 29; *Liles v. United States*, 638 F. Supp. 963 (D.D.C. 1986).

The Court of Appeals has identified four primary purposes of the exhaustion requirement:

> (1) it ensures that persons do not flout established administrative processes and thereby advances Congress' intent in establishing the processes;
>
> (2) it protects the autonomy of agency decisionmaking;
>
> (3) it aids judicial review by permitting factual development in an agency proceeding; and
>
> (4) it serves judicial economy by avoiding needless repetition of administrative and judicial factfinding and by perhaps avoiding the necessity of any judicial involvement if the parties successfully vindicate their claims before the agency.

Public Citizen Health Research Group v. Food and Drug Admin., 740 F.2d 21, 29 (D.C. Cir. 1984). Courts have routinely refused to consider claims when plaintiffs have not availed themselves of available administrative remedies prior to bringing suit. *See Mylan Pharmaceuticals, Inc. v. Henney, et al.*, Civ. No. 99-cv-862 (RMU), slip. op. at 12-14 (D.D.C. Mar. 31, 2000) (*Mylan II*) (attachment A hereto).

In *Public Citizen*, the Court of Appeals refused to make a judicial determination that aspirin without a Reye's Syndrome warning label was misbranded in the absence of final agency action. 740 F.2d at 33. Principles of "respect for the integrity of the administrative process – as embodied in the

exhaustion, finality, and ripeness doctrines" lead to the conclusion that judicial review is not available where FDA has not fully considered a citizen petition on a particular issue. *Id.* at 35; *see also Public Citizen v. Heckler*, 653 F. Supp. 1229, 1238 (D.D.C. 1986) (challenge to agency action was not considered because plaintiff did not exhaust administrative remedies by filing a petition with the agency prior to raising the issue in court); *Public Citizen v. Goyan*, 496 F. Supp. 364 (D.D.C. 1980) (case dismissed for failure to exhaust even after submission and denial of petition by plaintiff, because agency was engaged in rulemaking on subject presented to the court; court rejected claim that lack of factual issues made exhaustion inapplicable); *Public Citizen v. Foreman*, 471 F. Supp. 586, 594 (D.D.C. 1979) (color additive claims not presented to and addressed by FDA dismissed).

In the face of this settled law and FDA's regulation, Apotex essentially asks to be relieved of the exhaustion requirement without any justification.[2/] Not only is there no reason to

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[2/] Apotex incorrectly argues that exhaustion is not statutorily required in this case. Apotex's Application for Preliminary Injunction (Apotex App.), at 15, n.5. Apotex is incorrect because exhaustion is required by the APA, 5 U.S.C. § 704 ("Except as otherwise expressly provided by statute, agency action otherwise final is final for the purposes of this section ... unless the agency otherwise requires by rule and provides that the action meanwhile is inoperative, for an appeal to superior agency authority"). In urging the Court to disregard this statutory requirement, Apotex argues that FDA's regulation does not make the disputed administrative action inoperative

excuse Apotex's failure to exhaust administrative remedies in this case, curtailing the petition response time would deprive FDA of valuable public input in responding to Apotex's charges. The citizen petition process is public and interested parties are encouraged to submit comments on pending petitions. *See* 21 C.F.R. § 10.30(d). Indeed, SmithKline has indicated it intends to fully respond to Apotex's petition, but it has not yet done so. Thus, FDA would be deprived of comments from SmithKline and possibly others if Apotex is permitted to forego exhausting its administrative remedies.

Finally, because Apotex filed suit before obtaining a response to its administrative petition, there is no agency record for the Court to review. The Court of Appeals has specifically recognized that one of the primary purposes of the exhaustion requirement is the development of an administrative record to aid in judicial review. *Public Citizen*, 740 F.2d 21, 29. Apotex's attempt to circumvent the agency's citizen petition process flies in the face of established administrative and

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while an administrative appeal is pending. Apotex App. at 15, n.5. However, Apotex admits that, because of a stay on approval it does not contest, its application cannot be approved until December 2000. *Id.* at 9 (actually, it is November). Thus, Apotex is not now suffering its alleged harm, nor will it suffer such harm during the 180 days FDA has to respond to its citizen petition. Moreover, Apotex ignores 21 C.F.R. § 10.35, which permits requests to stay agency action.

judicial practice. For these reasons, Apotex's complaint should be dismissed.

III. Apotex Is Not Entitled To Preliminary Injunctive Relief

Should the Court reach the merits of plaintiff's motion for preliminary injunction, the motion should be denied because Apotex has failed to meet the requirements for preliminary injunctive relief. To obtain a preliminary injunction, a party must demonstrate: 1) a substantial likelihood of success on the merits; 2) it will suffer irreparable injury if the court does not grant the injunction; 3) an injunction would not substantially injure other interested parties (balancing the harms); and 4) granting the injunction would serve the public interest. *Mova*, 140 F.3d at 1066, *citing CityFed Fin. Corp. v. Office of Thrift Supervision*, 58 F.3d 738, 746 (D.C. Cir. 1995). The Court must balance the four factors in deciding whether to grant the injunction. *Mova*, 140 F.3d at 1066, *citing CityFed Fin.*, 58 F.3d at 747. A preliminary injunction is not granted as a matter of right. *Bristol-Myers Squibb Co. v. Shalala*, 923 F. Supp. 212, 215 (D.D.C. 1996) (*citing WMATC v. Holiday Tours, Inc.*, 559 F.2d 841, 843 (D.C. Cir. 1977)); *Eli Lilly and Co. v. Premo Pharm. Labs*, 630 F.2d 120, 136 (3d Cir.), *cert. denied*, 449 U.S. 1014 (1980). Injunctive relief is an extraordinary remedy and must be sparingly granted. *Dorfmann v. Boozer*, 414 F.2d 1168, 1173 (D.C. Cir. 1969).

A. Apotex Is Not Likely To Succeed On The Merits

The Court may set aside FDA's action in the instant case only if it is arbitrary, capricious, or not in accordance with the law. 5 U.S.C. § 706. This standard is highly deferential to the agency. *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). When reviewing FDA's interpretation of a provision of the FDCA, the Court must examine whether "Congress has directly spoken to the precise question at issue." *Chevron U.S.A. v. Natural Resources Defense Council*, 467 U.S. 837, 842-43 (1984). If Congress has not directly spoken to the precise question at issue, the Court must uphold FDA's construction of the provision if it is "permissible" under the statute. *Id.* at 843-44. Significantly, there may be more than one "permissible" construction, and the agency may adopt any permissible construction. *Id.* at 843 n.11 ("The Court need not conclude that the agency construction was the only one it permissibly could have adopted to uphold the construction, or even the reading the Court would have reached ....").

When courts are evaluating an agency's interpretations of its own regulations, the agency is entitled to "substantial deference." *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994); *Wyoming Outdoor Council v. U.S. Forest Service*, 165 F.3d 43, 52 (D.C. Cir. 1999). As the Court of Appeals recently noted:

> Our review in such cases is more deferential than that afforded under *Chevron*. The agency's construction of its own regulation is controlling unless it is plainly erroneous or inconsistent with the regulation. That broad deference is all the more warranted when the regulation concerns a complex and highly technical regulatory program.

Wyoming Outdoor Council, 165 F.3d at 52 (internal citations and quotations omitted); *see also Presbyterian Medical Center v. Shalala*, 170 F.3d 1146 (D.C. Cir. 1999); *Associated Builders and Contractors, Inc. v. Herman*, 166 F.3d 1248, 1253 (D.C. Cir. 1999).

Furthermore, the Court must look to the entire purpose of the Hatch-Waxman Amendments. "[I]n expounding a statute, we must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy." *Pilot Life Insurance Co. v. Dedeaux*, 481 U.S. 41, 51 (1987) (internal quotes omitted). *Accord McCarthy v. Bronson*, 500 U.S. 136, 139 (1991) (agreeing that, read in isolation, petitioner's reading was the most natural one but stating that "statutory language must always be read in its proper context"); *Massachusetts v. Morash*, 490 U.S. 107, 115 (1989); *Offshore Logistics, Inc. v. Tallentire*, 477 U.S. 207, 221 (1986); *Mastro Plastics Corp. v. NLRB*, 350 U.S. 270, 285 (1956) (rejecting literal interpretation of words in "complete isolation from their context in the Act").

"Where the literal reading of a statutory term would 'compel an odd result,' we must search for other evidence of congressional intent to lend the term its proper scope." *Public Citizen v. U.S. Dept. of Justice*, 491 U.S. 440, 454, (1989), (*quoting in part Green v. Bock Laundry Machine Co.*, 490 U.S. 504, 509 (1989)). Here, the Court should look to the totality of the statute and uphold FDA's regulation as reasonable a interpretation of the Hatch-Waxman Amendments.

1. Apotex Did Not Exhaust Its Administrative Remedies

As set forth above, Apotex has not exhausted its administrative remedies, because it instituted suit prior to receiving a response from FDA to its administrative petition. Because Apotex has not yet exhausted its administrative remedies, Apotex is unlikely to succeed on the merits of its claim. *See Mylan II*, slip op. at 13 ("Having failed to exhaust its administrative remedies regarding claims of entitlement to exclusivity, Mylan can not demonstrate the requisite likelihood of success on the merits for an injunction."). Thus, Apotex's motion should be denied.

2. FDA Has Properly Construed § 355(b) and (c)

Even if Apotex is excused from exhausting its administrative remedies, its motion for preliminary injunction should be denied because it is unlikely to succeed in showing that FDA's interpretation of the patent provisions in the FDCA is incorrect.

Apotex asserts that FDA improperly listed patents '132 and '423 because they were issued more than six years after Paxil® was approved. Apotex App. 24-27. Because the statute compels this result, Apotex's claim must be rejected.

New drug applications filed with FDA must contain, among other things, "the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). The statute continues: "If an application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by the preceding sentence." *Id.* Thus, the statute specifically directs applicants to include existing patent information at the time an NDA is filed, and amend the NDA to include any patent information obtained while the NDA is pending.

The statute also makes provision for a third contingency - patents issued after an application has been approved. "If the patent information described in [21 U.S.C. § 355(b)] could not be filed with the submission of an application ... because ... a

'423 fit the second circumstance described in the statute; they had not yet been obtained by SmithKline at the time the Paxil® NDA was filed with and approved by FDA. Thus FDA properly filed the patents, in accordance with the clear statutory directive.

As Apotex points out, FDA recognized the potential for abuse by serially listing patents. *See* Apotex App. at 11. However, there is a solution. First, FDA required that patent information be filed promptly with FDA, within 30 days after issuance of the patent. 21 C.F.R. § 314.53(d)(3). Second, while Congress provided for a presumptive 30-month statutory stay upon the filing of a timely patent infringement suit, it also provided that the 30-month period could be modified by the court hearing the patent litigation. 21 U.S.C. § 355(j)(5)(B)(iii). Thus, Apotex's remedy is *not* to sue FDA for complying with the statute but rather, as provided by the statute, ask the Pennsylvania court hearing its patent litigation to modify the 30-month stay. If the patent issues are as clear as Apotex argues, the patent court should rule on the matter expeditiously. The plain language of the FDCA does not support Apotex's proposed construction of the statute. Thus, Apotex is unlikely to succeed on the merits of its claim, and its motion for preliminary injunction should be denied.

patent was issued after the application was approved ... the holder of an approved application shall file with the Secretary the patent number and the expiration date of any patent which claims the drug for which the application was submitted or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(c)(2). Information regarding patents issued after NDA approval must be filed with FDA within 30 days of patent issuance. 21 C.F.R. § 314.53(d)(3).

In arguing that late-obtained patents should only be listed if the patents could not have been obtained prior to the submission of an NDA (Apotex App. at 25), Apotex attempts to read a requirement into the statute that simply is not there. The first clause of § 355(c)(2), "If the patent information described in [21 U.S.C. § 355(b)] could not be filed with the submission of an application" cannot be read without reference to the end of the sentence. The statute provides two reasons why patent information may not have been filed under 21 U.S.C. § 355(b): (1) the information was not required at the time the NDA was filed;[3] or (2) the patent had not yet been obtained. Patents '132 and

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[3] The legislative history Apotex cites in support of a narrow construction of § 355(c) (Apotex App. at 26, n.11), clearly pertains to the first circumstance described in the statute rather than the second, and that first scenario is not relevant to this case.

'423 fit the second circumstance described in the statute; they had not yet been obtained by SmithKline at the time the Paxil® NDA was filed with and approved by FDA. Thus FDA properly filed the patents, in accordance with the clear statutory directive.

As Apotex points out, FDA recognized the potential for abuse by serially listing patents. *See* Apotex App. at 11. However, there is a solution. First, FDA required that patent information be filed promptly with FDA, within 30 days after issuance of the patent. 21 C.F.R. § 314.53(d)(3). Second, while Congress provided for a presumptive 30-month statutory stay upon the filing of a timely patent infringement suit, it also provided that the 30-month period could be modified by the court hearing the patent litigation. 21 U.S.C. § 355(j)(5)(B)(iii). Thus, Apotex's remedy is *not* to sue FDA for complying with the statute but rather, as provided by the statute, ask the Pennsylvania court hearing its patent litigation to modify the 30-month stay. If the patent issues are as clear as Apotex argues, the patent court should rule on the matter expeditiously. The plain language of the FDCA does not support Apotex's proposed construction of the statute. Thus, Apotex is unlikely to succeed on the merits of its claim, and its motion for preliminary injunction should be denied.

3. 21 C.F.R. § 314.53(f) Is Consistent With The FDCA

Apotex further claims that FDA's regulation governing the correction of listed patent information, 21 C.F.R. § 314.53(f), is contrary to Congressional intent. Apotex App. at 27-31. Apotex's argument is without merit.

By regulation, FDA has informed interested parties what patent information is to be submitted, who must submit the information, and when and where to submit the information. 21 C.F.R. § 314.53(a), (b), (c), and (d). FDA's regulation also sets forth a process for correcting patent information errors. *Id.* at § 314.53(f). In the event of a dispute as to the accuracy or relevance of patent information, a written notification of the grounds for dispute must be sent to FDA. *Id.* FDA then requests the NDA holder to confirm the correctness of the patent information. *Id.* Unless the patent information is withdrawn or amended by the NDA holder, FDA will not change the patent information listed in the Orange Book. *Id.*[4/]

As explained at length in the proposal for § 314.53, FDA's role in listing patents is purely ministerial; FDA does not have the expertise nor the resources to resolve complex patent coverage issues. 54 Fed. Reg. 28872, 28909-10 (July 10, 1989). Furthermore, FDA's approach to listing patents is fully

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[4/] Apotex did not avail itself of this procedure.

consistent with how Congress intended the agency to implement the Hatch-Waxman Amendments. *Id.*

Two comments on FDA's proposal regarding implementation of the Hatch-Waxman Amendments asserted that "FDA should ensure that patent information submitted to the agency is complete and applies to a particular NDA." 59 Fed. Reg. 50338, 50345 (Oct. 3, 1994). In response, FDA reiterated that it does not have the resources or the expertise to review patent information for its accuracy and relevance to an NDA. *Id.*, *see also id.* at 50342-43, 50345, 50349, 50352. Thus, FDA carefully considered and rejected the role Apotex now seeks to have FDA fill.

This case presents an example of why it would be so difficult for FDA to adjudicate patent coverage disputes. In its administrative petition, Apotex acknowledges that there is judicial precedent that is contrary to the argument it makes to the agency regarding the propriety of listing patents '132 and '423. *See* Apotex Compl., Exh. N, at 21-22. Also, Apotex is in the midst of litigation with SmithKline over patent '423 in the United States District Court for the Eastern District of Pennsylvania. Apotex Compl., Exh. M. Presumably, Apotex has raised the issue of whether patent '423 covers Paxil® and, therefore, was properly listed by FDA. Yet Apotex asks FDA, and now this Court, to enter the fray and render an opinion about whether patents '132 and '423 cover Paxil®, and this Court should

reject this attempt. *Cf. Apotex, Inc. v. Shalala*, 53 F. Supp. 2d 454, 463 (D.D.C. 1999) (this Court rejected Apotex's attempt to force FDA and the Court to examine and analyze coverage of prior patent litigation).

Not only is Apotex's manner of proceeding inefficient in terms of duplication of effort by FDA and this Court, it may result in conflicting decisions. What if the Pennsylvania court rules the patents were properly listed but this Court rules they were not? For this very reason, FDA rejected the approach proposed by Apotex, and instead responds to private patent litigation decisions.

Because FDA's process for listing patent information and for correcting patent information errors is consistent with Congressional intent, it should be left undisturbed. For these reasons, Apotex's motion for preliminary injunction should be denied.

B. Irreparable Harm

To obtain preliminary relief, Apotex must demonstrate that it will suffer irreparable injury if its request is not granted. Irreparable injury is a "very high standard." *See Varicon Int'l v. Office of Personnel Management*, 934 F. Supp. 440, 447 (D.D.C. 1996); *American Coastal Line Joint Venture, Inc. v. United States Lines, Inc.*, 580 F. Supp. 932, 936 (D.D.C. 1983). A party must demonstrate that it will suffer certain, imminent, and

irreparable injury without the requested relief. *Wisconsin Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985). In addition, economic loss in and of itself does not constitute irreparable injury, *Wisconsin Gas*, 758 F.2d at 674, and the alleged injury must be significant in relation to the business of the party seeking relief. *See WMATC v. Holiday Tours Inc.*, 559 F.2d 841, 843 n. 3 (D.C. Cir. 1977).

Apotex will not be irreparably injured if it does not receive its requested preliminary injunction. Apotex admits that its application cannot be approved until December 2000 (actually November), at the earliest, as a result of a 30-month statutory stay it does not contest. Apotex App. at 9. Moreover, Apotex's delay in bringing suit, waiting approximately a year from the time patents '132 and '423 were filed and six months after it was sued by SmithKline on patent '423, is a clear indication that it has not suffered an irreparable injury. *See Mylan I*, 81 F. Supp.2d 30, 44. Thus, Apotex cannot be irreparably harmed by the denial of its motion for preliminary injunction.

Second, while Apotex argues its resources are being depleted by patent litigation with SmithKline (Apotex App. at 31), it does not even allege that this financial drain is an economic injury "sufficiently large in proportion" to its operations so that the amount of money lost would cause "extreme hardship to the business, or even threaten destruction of the business." *See*

Gulf Oil Corp. v. Department of Energy, 514 F. Supp. 1019, 1025 (D.D.C. 1981).

Apotex also claims it may injured because it may lose the ability to take advantage of 180 days of market exclusivity if it is subject to an additional 30-month stay. Apotex App. at 32. This claim is too speculative to support a finding of irreparable injury because it depends on the timing of the decisions in Apotex's patent litigations involving patents '723 and '423. There is simply no way to ascertain the timing of a decision in either patent litigation. Moreover, Apotex would have to prevail in its patent litigation in order to trigger its exclusivity. A finding of irreparable injury cannot rest on such an uncertain result. Finally, as discussed above, Apotex could ask the Pennsylvania court to modify the 30-month statutory stay period. For all of these reasons, the potential loss of 180 days of exclusivity is too speculative to support the entry of a preliminary injunction.

C. Balance of Harms and the Public Interest

A party seeking a preliminary injunction must show that in balancing the harms in granting versus denying the injunction, the harm it will suffer outweighs the potential harm to the other affected parties. Apotex argues that the balance of harms weighs in its favor. However, as set forth above, the injuries proposed

by Apotex are simply too speculative to form the basis of a finding of irreparable harm. *See* Apotex App. at 12-14.

Furthermore, Apotex is incorrect that FDA will not be harmed by the entry of an injunction. FDA would be harmed by a disruption of its processes for listing patents and resolving disputes related to listed patents if a preliminary injunction is entered. *Mylan II*, slip op. at 36.

Finally, Apotex has failed to demonstrate that a preliminary injunction would serve the public interest. Apotex states that a preliminary injunction would serve the public interest by enhancing competition. Apotex App. at 33. FDA agrees that the public is served by the timely entry of lower cost, safe and effective generic drug products. However, granting Apotex's preliminary injunction in this case would not serve the public interest. The public interest, as expressed by Congress, requires FDA to list patents obtained after application approval, as long as the patent information is filed in a timely manner. Apotex's interpretation would upset the careful balance crafted by Congress, between encouraging the marketing of generic drugs and rewarding innovator companies for their research and development of new drugs. Thus, Apotex's argument that the public interest favors a preliminary injunction should be rejected.

CONCLUSION

For the foregoing reasons, Apotex's request for preliminary injunction should be denied, and this case should be dismissed.

Respectfully submitted,

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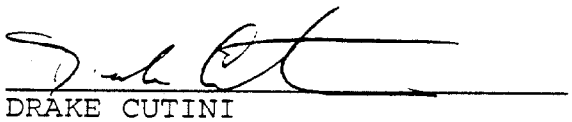

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April 12, 2000.

CERTIFICATE OF SERVICE

I hereby certify that on April 12, 2000, I caused a copy of the foregoing Defendants' Memorandum in Opposition to Plaintiff's Application for Preliminary Injunction and In Support of Defendants' Motion to Dismiss to be served, by facsimile and first class mail, upon the following:

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

APOTEX, INC., Plaintiff, v. DONNA E. SHALALA, et al., Defendants.	Civ. No. 1:00CV00729 (TPJ)

FEDERAL DEFENDANTS' REPLY IN SUPPORT OF MOTION TO DISMISS

INTRODUCTION

Plaintiff Apotex, Inc., seeks to manufacture a generic version of paroxetine hydrochloride. Apotex alleges that the Food and Drug Administration (FDA) improperly "listed" two patents with respect to the innovator paroxetine hydrochloride product. The innovator version of this product is manufactured by SmithKline Beecham (SmithKline) under the brand name Paxil. Apotex submitted its Abbreviated New Drug Application (ANDA) to manufacture paroxetine hydrochloride in 1998, and certified that its product would not infringe the patent then listed for the product, patent '723. SmithKline sued Apotex for patent infringement, and this lawsuit resulted in a 30-month stay during which Apotex's product cannot be approved. This 30-month stay expires in November, 2000, and Apotex does not challenge this stay. Thus, Apotex does not dispute the fact that its product cannot be approved prior to November of this year.

In 1999, SmithKline was issued other patents ('132 and '423) and it submitted those to FDA claiming its Paxil product. Apotex submitted certifications to FDA stating that its ANDA product did not infringe these patents, and SmithKline sued Apotex in the Eastern District of Pennsylvania on the '423 patent. This litigation is ongoing. This litigation resulted in a second 30-month stay of approval of Apotex's ANDA, and Apotex alleges injury as a result of this second 30-month stay. However, this second 30-month stay can have no operative effect on Apotex until the expiration of the first 30-month period in November, 2000.

Additionally, SmithKline asserts that it has sued two other generic manufacturers on this same issue in the Eastern District of Pennsylvania, Geneva Pharmaceuticals and Zenith Pharmaceuticals. SmithKline asserts that Geneva and Zenith have raised the "patent listing" issue in the Pennsylvania litigation.

As explained in greater detail below, this case is not ripe because Apotex's ANDA cannot by law be approved prior to November, 2000, and thus Apotex cannot suffer its alleged injury until that time. Further, Apotex has failed to exhaust administrative remedies, and its complaint can also be dismissed for that reason. Finally, should the Court reach the substance of Apotex's complaint, the complaint should be dismissed because it fails to state a claim upon which relief can be granted. Apotex alleges that patents '132 and '423 were improperly listed

because these patents do not properly claim SmithKline's paroxetine hydrochloride product and that FDA should "de-list" these patents. However, Apotex has failed to demonstrate that FDA has any responsibilities under the Food, Drug, and Cosmetic Act (FDCA) other than those it has exercised in this case. FDA is not required under the FDCA to review and analyze patents nor to make determinations of patent applicability. Those decisions are appropriately raised in private patent litigation, as Geneva and Zenith have done. For these reasons, this case should be dismissed.

ARGUMENT

I. THERE IS NO RIPE CASE OR CONTROVERSY BEFORE THIS COURT

As demonstrated in defendants' memorandum in support of their motion to dismiss, Apotex's ANDA cannot be approved until November 21, 2000, because of the statutory 30-month stay with respect to patent '723, which stay Apotex does not challenge. In its opposition to defendants' motion to dismiss, Apotex does not dispute this fact. Nonetheless, Apotex argues that this case is ripe because it is suffering "tangible harm;" i.e., litigation expense and a second 30-month stay. Apotex Opp. at 22. However, Apotex does not dispute that the second 30-month stay cannot possibly have any effect on the approval of Apotex's product until the first 30 months expires in November 2000. Thus, the "second" 30-month stay is not causing any present harm.

Significantly, the second 30-month period can be shortened by the court hearing the patent case. 21 U.S.C. § 355(j)(5)(B)(iii). Apotex does not dispute that it could seek to expedite the patent litigation – which should be easy if this case is really as easy as Apotex alleges. Thus, it is possible that the patent litigation on the '423 patent will be resolved before the unchallenged 30-month period expires in November 2000, and that Apotex's ANDA approval will not be delayed beyond November 21, 2000 – a delay that it does not challenge. Because of these contingent events, Apotex's claim is not ripe. "A claim is not ripe for adjudication if its rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." Texas v. United States, 523 U.S. 296, 300 (1998); Pfizer Inc. v. Shalala, 182 F.3d 975, 978 (D.C. Cir. 1999).

These facts serve to distinguish this case from the Mylan case relied on by Apotex. Apotex Opp. at 27. In Mylan Pharmaceuticals, Inc. v. Shalala, 81 F. Supp.2d 30 (D.D.C. 2000), FDA had tentatively approved Mylan's ANDA, id. at 35, which meant that the product was "approvable" in all respects except for the exclusivity period of a competitor, and that exclusivity period was what Mylan challenged. In other words, Mylan's product could have been approved immediately but for the FDA decision challenged in that case. That is clearly not true in the instant

case: even without the second 30-month period, Apotex could not be approved until November 2000.

Apotex argues that the issues it raises are "purely legal" because FDA's position is "both 'definitive' and 'final'" and the issues are thus ripe for review. Apotex Opp. at 24. However, even if FDA's position were "final" and the issues "purely legal," it would not mean that Apotex is suffering an Article III injury. "[A] final agency action nonetheless can be unripe for judicial review." Pfizer, Inc., 182 F.3d at 980. In order for a ripe controversy to exist, there must not only be final agency action, its effects must be "felt in a concrete way by the challenging parties." Abbott Laboratories v. Gardner, 387 U.S. 136, 148-49 (1967). In the instant case Apotex is suffering no "concrete" injury as a result of the listing of patents '132 and '423 (it has not even been sued with respect to patent '132). In addition, FDA has not rendered a final decision on the citizen petition filed by Apotex, and FDA's response is not due until August, 2000. If Apotex is permitted to bypass this citizen petition procedure – a procedure that Apotex initiated – FDA would be deprived of public comments, and there would be no record for this Court to review.

The only immediate harm that Apotex alleges is its litigation expense in defending patent litigation brought by SmithKline. Apotex Opp. at 22, 25. However, in Pfizer, Inc.,

Pfizer similarly argued that its litigation expense was an Article III injury because it would not be incurring such expense if FDA had not accepted the ANDA of Mylan Pharmaceuticals. This argument was rejected by the Court. 182 F.3d at 979. Similarly, the Supreme Court has held that litigation expense is not a sufficient injury to invoke the judicial power of the United States courts. FTC v. Standard Oil Co., 449 U.S. 232 (1980). Neither of the two cases cited by Apotex for its "litigation expense" argument, Apotex Opp. at 25, held that litigation expense was sufficient to create an Article III case or controversy.[1/]

II. APOTEX FAILED TO EXHAUST ITS ADMINISTRATIVE REMEDIES

Apotex filed a citizen petition with FDA on February 3, 2000, almost a year after Apotex became aware of the FDA action it challenges (the listing of the '132 and '423 patents), and six months after Apotex was sued by SmithKline for infringing one of those patents. FDA's regulations provide that FDA is to respond to citizen petitions within 180 days, 21 C.F.R. § 10.30(e)(2). Apotex requested that FDA respond to its petition in just 26

[1/] In Electronic Data Systems Federal Corp. v. GSA, 629 F. Supp. 350, 352 (D.D.C. 1986), the court discussed the litigation burden on amicus Government Printing Office in the context of irreparable harm for preliminary relief, and in United Steel Workers of America, AFL-CIO-CLC v. USX Corp., 966 F.2d 1394, 1404 n.32 (11th Cir. 1992), the court held that plaintiff was not entitled to preliminary relief while noting that plaintiff could have avoided its "substantial litigation expense" by utilizing arbitration.

days, by February 29, 2000. Under its regulation, FDA's response to Apotex's petition is due August 3, 2000, five months before Apotex could even begin to suffer its alleged harm.

Apotex has not, and cannot, put forth any legitimate reason for not exhausting its administrative remedies as required by the APA and 21 C.F.R. § 10.45. See Mylan Pharmaceuticals, Inc. v. Henney, et al., Civ. No. 99-cv-862 (RMU), Slip. Op. at 13 (D.D.C. Mar. 31, 2000) (an issue that Mylan failed to raise in response to a citizen petition "is not the proper subject of judicial review" because Mylan "failed to exhaust" with respect to that issue) (this slip opinion is attachment A to defendants' memorandum in support of motion to dismiss).

Apotex argues that exhaustion would be futile because FDA's regulation, 21 C.F.R. § 314.53(f), does not provide Apotex any relief. Apotex Opp. at 28. However, while FDA is not likely to invalidate its own regulation, that is not the only issue raised by Apotex. Apotex argues that FDA should not have listed the '423 and '132 patents submitted by SmithKline. While it is not clear what FDA's response to this allegation will be, that issue will no doubt be addressed in some manner in the citizen petition process. The citizen petition process is public and interested parties may well address this issue. See 21 C.F.R. § 10.30(d). SmithKline has indicated that it intends to submit comments on Apotex's citizen petition. Curtailing the petition response time

would deprive FDA of valuable public input in responding to Apotex's charges. Because Apotex filed suit before obtaining a response to its petition, there is no agency record for the Court to review. The Court of Appeals has specifically recognized that one of the primary purposes of the exhaustion requirement is the development of an administrative record to aid in judicial review. Public Citizen Health Research Group v. FDA, 740 F.2d 21, 29 (D.C. Cir. 1984).

Apotex argues that exhaustion is not statutorily required in this case because the challenged agency action is not rendered "inoperative" during the administrative process. Apotex Opp. at 29. However, Apotex does not dispute that because of a stay on approval it does not contest, its application cannot be approved until November 2000. Thus, Apotex is not now suffering any harm, nor will it suffer such harm during the 180 days FDA has to respond to its citizen petition. In this regard this case is distinguishable from Bracco Diagnostics, Inc. v. Shalala, 963 F. Supp. 20 (D.D.C. 1997), cited by Apotex. Apotex Opp. at 30. In Bracco, the Court held that exhaustion was not necessary because FDA could approve the competitor before FDA's citizen petition response was due. Id. at 31. Here, by contrast, the citizen petition response is due months before Apotex could be approved.

For these reasons, Apotex's attempt to circumvent the

citizen petition process that it initiated should be rejected, and its complaint should be dismissed.

III. APOTEX'S COMPLAINT SHOULD BE DISMISSED

Apotex's principal argument is that the '423 patent does not claim the approved paroxetine hydrochloride drug and therefore FDA should not have listed the patent. Apotex argues that SmithKline's approved NDA is paroxetine hydrochloride hemihydrate and that the '423 patent pertains to paroxetine hydrochloride anhydrate. Apotex Opp. at 7-8 (anhydrate or anhydrous means without water). Apotex argues that the '423 patent claims a different active ingredient from that of the NDA. Id. at 8.

However, the product that is the subject of Apotex's own ANDA is an anhydrous product. See, e.g., Complaint ¶ 30. Thus, both Apotex's product and the product claimed by the '423 patent are anhydrous products. While it is arguing that the '423 patent cannot claim the approved NDA because the patent pertains to an anhydrous product, Apotex's very own ANDA – which it seeks to have approved as a pharmaceutical equivalent to the NDA – is for an anhydrous product. Among other things, to be approved as a pharmaceutical equivalent, an ANDA must have the same active ingredient as the NDA. 21 U.S.C. §§ 355(j)(2)(C), 355(j)(4)(C). Thus, Apotex is arguing that its own anhydrous product has the same active ingredient as SmithKline's hemihydrate product, while at the same time asserting that the '423 patent cannot claim the

same active ingredient as the NDA because one is anhydrous and one is a hemihydrate.

In response to this argument, Apotex argues that whether two products are the same for ANDA approval purposes is different from whether a patent covers two versions of the same active ingredient. Apotex Opp. at 10-11. While this may be true, the significant factor is that while FDA does have a responsibility to analyze whether a generic product is the "same" as an innovator product for Hatch-Waxman purposes, FDA has no responsibility to analyze the scope and application of patents, as argued by Apotex.

In this regard, Apotex argues that FDA has improperly delegated "its responsibility to receive, review, and list appropriate patents under the Act." Apotex Opp. at 15 (heading), 18, 21. Apotex quotes no statutory language that gives FDA the responsibilities that Apotex imagines. Apotex cites 21 U.S.C. § 355(b)(1) and (c)(2), but an examination of those sections does not reveal an imposition of responsibilities on FDA beyond what it exercises. The first section cited by Apotex, § 355(b)(1), states that the applicant shall file with its NDA "the patent number and the expiration date of any patent which claims the drug...." The only thing FDA is directed to do under this section regarding patents is to publish the information. The other section cited by Apotex, § 355(c)(2), similarly places no

responsibilities on FDA other than to publish the submitted information.

Thus, Congress gave FDA no "review" responsibility, as alleged by Apotex, and FDA does not improperly delegate its regulatory responsibility. By regulation, FDA has implemented the statute by informing interested parties what patent information is to be submitted, who must submit the information, and when and where to submit the information. 21 C.F.R. §§ 314.53(a), (b), (c), and (d). Apotex takes issue with FDA's regulation which sets forth a process for correcting patent information errors. Id. at § 314.53(f). In the event of a dispute as to the accuracy or relevance of patent information, a written notification of the grounds for dispute must be sent to FDA. Id. FDA then requests the NDA holder to confirm the correctness of the patent information. Id. Unless the patent information is withdrawn or amended by the NDA holder, FDA will not change the patent information listed in the Orange Book. Id.[2/] As explained in federal defendants' initial memorandum, FDA's role in listing patents is purely ministerial; FDA does not have the responsibility, the expertise, nor the resources to resolve complex patent coverage issues. See Defendants' Memorandum at 23-25; 54 Fed. Reg. 28872, 28909-10 (July 10, 1989). FDA's approach to listing patents is fully consistent

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[2/] Apotex did not avail itself of this procedure.

with the manner in which Congress intended the agency to implement the Hatch-Waxman Amendments. See 21 U.S.C. § 355(b)(1), (c)(2) (FDA "shall publish" the patent information).[3/]

Apotex also argues that FDA cannot list additional patents in the Orange Book after approving an NDA when there is at least one patent listed. Apotex Opp. at 9. In support of this assertion, Apotex cites 21 U.S.C. § 355(c)(2). Significantly, Apotex does not quote any language from this statutory section that it alleges precludes SmithKline from listing patents '423 and '132. An examination of that language reveals that the statute explicitly permits what Apotex challenges: "If the patent information described in [21 U.S.C. § 355(b)] could not be filed with the submission of an application ... because ... a patent was issued after the application was approved ... the holder of an approved application shall file with the Secretary the patent number and the expiration date of any patent which claims the drug ...." 21 U.S.C. § 355(c)(2). Information regarding patents issued after NDA approval must be filed with

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[3/] Contrary to Apotex's suggestion, FDA's action in conveying information to the Patent and Trademark Office is just as ministerial as FDA's publishing of patent information for NDAs. See Apotex Opp. at 21. The letter to which Apotex refers did not, as Apotex asserts, constitute a "review" of patent '723 to confirm that patent '723 accurately "claimed" Paxil. The letter merely conveyed public information, i.e., that FDA had listed patent '723 for Paxil, that the product was subject to FDA's regulatory review, and that the product had not been used or marketed previously.

FDA within 30 days of patent issuance. 21 C.F.R. § 314.53(d)(3). Thus, Apotex's "timing" argument must be rejected under the explicit terms of the statute.[4/]

Apotex also argues that FDA, not patent courts, must settle the question of whether the '423 patent correctly "claims" Paxil. Apotex Opp. at 18. Yet, the precise issue raised by Apotex in the instant case has already been raised before Judge Kauffman in the Eastern District of Pennsylvania, who is hearing the patent case between Apotex and SmithKline. See Memorandum of Intervenor SmithKline Beecham Corporation in Opposition to Plaintiff's Motion for a Preliminary Injunction at 4. SmithKline asserts that it has sued Geneva Pharmaceuticals and Zenith Pharmaceuticals, as well as Apotex, in the Eastern District of Pennsylvania with regard to the same patents. Id. SmithKline also asserts that both Geneva and SmithKline have challenged the Orange Book listings in that litigation. Id.

Yet Apotex asks FDA, and now this Court, to enter the fray and render an opinion about whether patents '132 and '423 correctly claim Paxil®. This Court should reject this attempt. Cf. Apotex, Inc. v. Shalala, 53 F. Supp. 2d 454, 463 (D.D.C. 1999), summarily aff'd, No. 99-5231, 1999 WL 956686 (D.C. Cir. Oct. 8, 1999) (this Court rejected Apotex's attempt to force FDA

[4/] Other aspects of this argument are discussed in defendants' initial memorandum at pages 19-22.

and the Court to examine and analyze coverage of prior patent litigation).

Significantly, the issue of "de-listing" patents has arisen in other cases, and it has arisen in situations similar to the one here, i.e., hydration differences between the approved product and the patent. In these other cases, however, the private parties raised the issue in the appropriate forum: private patent litigation that did not involve the FDA.

In Zenith Laboratories, Inc. v. Abbott Laboratories, Civ. No. 96-1661 (D.N.J. Aug. 7, 1996) (this slip opinion is attachment J to Apotex's citizen petition, and the citizen petition is attachment A to the affidavit of Scott Feder, which was submitted by Apotex with its complaint), Zenith argued that Abbott had improperly listed patents in the Orange Book in order to keep Zenith off the market for 30 months and to subject Zenith to patent litigation. Slip Op. at 6. Abbott marketed a dihydrate form of terazosin hydrochloride as Hytrin. Abbott listed other patents in the Orange Book for Hytrin that claimed anhydrous forms of terazosin hydrochloride. Id. Zenith sought to market an anhydrous form of terazosin hydrochloride. Id. at 7. Zenith claimed that the patents in question pertained to anhydrous forms of terazosin hydrochloride and they could not claim the approved product, Hytrin, because Hytrin was a dihydrate form. Id. at 19.

In rejecting Zenith's claim, the court noted that FDA's Orange Book provides that "anhydrous and hydrated entities are considered pharmaceutical equivalents." Id. at 23. The court also stated that if "these polymorphs do have the same dissolution, solubility and absorption as that found within the drug substance in Hytrin," the listing of the patents "would be correct." Id. at 25. However, the court held that there was a question of fact whether the different forms of terazosin hydrochloride were the same, and summary judgment was not appropriate. Id. at 24.

Similar results were reached in Ben Venue Laboratories, Inc. v. Novartis Pharmaceutical Corp, 10 F. Supp.2d 446 (D.N.J. 1998). Ben Venue, a generic drug manufacturer, sought a preliminary injunction to have the innovator company (Novartis) remove a patent from FDA's Orange Book. Ben Venue argued that the patent (the '880 patent) did not claim the listed drug (Aredia) because the patent claimed the crystalline pentahydrate form of pamidronate but the actual product did not contain the pentahydrate form of pamidronate. Id. at 453. Novartis admitted that the final drug product did not contain the pentahydrate form, but was anhydrous. Id. Nonetheless, Novartis argued that the patent was properly listed in the Orange Book because it pertained to the drug substance of Aredia. Id. The court agreed with Novartis, and concluded that "the '880 patent is very likely

properly listed in the Orange Book" and thus denied the preliminary injunction. Id. at 458.

Apotex's reliance on the Pfizer case is also misplaced. Apotex Opp. at 20. In Pfizer v. FDA, 753 F. Supp. 171 (D. Md. 1990), Pfizer had an approved NDA for a nifedipine capsule, for which it had two patents listed. However, it attempted to submit a third patent for a nifedipine tablet. FDA refused to list this patent because it did not pertain to the approved product, which was a capsule. Id. at 174-75. This decision was consistent with § 355(b)(1), which requires the applicant to submit patent information for any patent which claims the drug "for which the applicant submitted the application," and an application to manufacture a capsule is not the same as an application to manufacture a tablet. The court granted summary judgment in FDA's favor. Id. at 178. A tablet is a different dosage form than a capsule, and under the FDCA different dosage forms are different products. See Warner-Lambert Co. v. Shalala, 202 F.3d 326 (D.C. Cir. 2000); Pfizer Inc. v. Shalala, 182 F.3d 975.

Significantly, FDA has recognized the potential for abuse by serially listing patents. However, as the defendants stated in their initial memorandum, there is a solution. First, FDA required that patent information be filed promptly with FDA, within 30 days after issuance of the patent. 21 C.F.R. § 314.53(d)(3). Second, while Congress provided for a

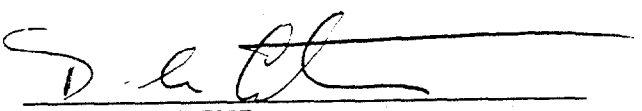
presumptive 30-month statutory stay upon the filing of a timely patent infringement suit, it also provided that the 30-month period could be modified by the court hearing the patent litigation. 21 U.S.C. § 355(j)(5)(B)(iii). Thus, Apotex's remedy is not to sue FDA for complying with the statute but rather, as provided by the statute, ask the Pennsylvania court hearing its patent litigation to modify the 30-month stay. If the patent issues are as clear as Apotex argues, the patent court should rule on the matter expeditiously.

CONCLUSION

For the foregoing reasons, Apotex's complaint should be dismissed.

Respectfully submitted,

DAVID W. OGDEN
Acting Assistant Attorney General



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May 3, 2000.

CERTIFICATE OF SERVICE

I hereby certify that on May 3, 2000, I caused a copy of the foregoing Defendants' Reply Memorandum in Support of Defendants' Motion to Dismiss to be served, by hand delivery, upon the following:

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

APOTEX, INC.,

Plaintiff,

v.

DONNA E. SHALALA,
SEC'Y OF HEALTH AND HUMAN SERVICES, et al.,

Defendants.

SMITHKLINE-BEECHAM CORP.

Defendant-Intervenor.

C.A. No. 00-0729 (TPJ)

ORDER

Upon consideration of plaintiff's application for a preliminary injunction, and of defendants' and defendant-intervenor's oppositions thereto, for essentially the reasons set forth on the record in open court at the motions hearing of May 15, 2000, it is this 15th day of May, 2000,

ORDERED, that plaintiff's application for a preliminary injunction is denied.

Thomas Penfield Jackson
U.S. District Judge

#2

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

APOTEX, INC. PLAINTIFF,	:	
VS.	:	C. A. NO. 00-729
DONNA E. SHALALA, SEC. OF HHS DEFENDANT,	:	

WASHINGTON, D. C.
MAY 15, 2000

TRANSCRIPT OF PROCEEDINGS
BEFORE THE HONORABLE THOMAS P. JACKSON

FOR THE PLAINTIFF:	PETER WORK, ESQ. HUGH MOORE, ESQ. TERRENCE CANADE, ESQ.
FOR THE DEFENDANT:	DRAKE CUTINI, ESQ. KIM DETTELBACH, ESQ.
FOR THE MOVANT:	BRUCE KUHLIK, ESQ.
COURT REPORTER:	PHYLLIS MERANA 6816 U. S. COURTHOUSE 3RD & CONSTITUTION AVE., N.W. WASHINGTON, D. C. 20001

P-R-O-C-E-E-D-I-N-G-S.

THE DEPUTY CLERK: CIVIL ACTION 00-729, APOTEX, INC. VERSUS DONNA SHALALA, SECRETARY OF HHS.

PETER WORK, HUGH MOORE, AND TERRENCE CANADE FOR THE PLAINTIFF.

DRAKE CUTINI AND KIM DETTELBACH FOR THE DEFENDANT.

MR. WORK: GOOD MORNING, YOUR HONOR.

THE COURT: GOOD MORNING.

MR. WORK: MY NAME IS PETER WORK. I AM WITH CROWELL & MORING.

I WOULD LIKE TO INTRODUCE MY COLLEAGUES, MR. HUGH MOORE AND MR. TERRENCE CANADE. I HAVE MOVED THEIR ADMISSION IN THIS MATTER PRO HAC VICE.

THE COURT: YOU HAVE, INDEED. I HAVE THAT ON TOP OF MY FILE. AND THE MOTION IS GRANTED.

MR. WORK: THANK YOU, YOUR HONOR.

THE COURT: I AM GLAD TO HAVE YOU, GENTLEMEN.

MR. WORK: MR. MOORE WILL BE MAKING THE ARGUMENT THIS MORNING.

THE COURT: ALL RIGHT.

MR. MOORE: GOOD MORNING, YOUR HONOR.

THE COURT: GOOD MORNING, MR. MOORE.

MR. MOORE: THIS CASE IS ABOUT WHETHER, PERHAPS, AND CERTAINLY WHEN THERE WILL EVER BE GENERIC COMPETITION FOR PAXIL, WHICH COSTS THE AMERICAN TAXPAYERS 1.3 BILLION

DOLLARS A YEAR.

NOW, ON THE MERITS OF THIS CASE, I HAVE NOT ENCOUNTERED IN THE RECENT PAST A CASE IN WHICH THE ISSUES WERE SO CLEAR, THE FACTS SO FEW, AND THE FACTS SIMPLY UNDISPUTED.

I THOUGHT, FIRST OF ALL, THAT IT WOULD BE HELPFUL, IF I TALKED FOR JUST A MOMENT ABOUT THE PATENT ISSUES IN THE CASE. AND WE HAVE PREPARED -- AND I HAVE PROVIDED TO COUNSEL FOR THE DEFENDANTS -- A SMALL GRAPHIC DEPICTION OF THE PATENTS THAT ARE IN THE BACKGROUND OF THIS CASE.

(PASSING UP TO THE COURT.)

MR. MOORE: NOW, YOUR HONOR, ON THE LEFT-HAND SIDE, COLORED IN YELLOW, IS A REFERENCE TO A PATENT THAT I WOULD LIKE TO REFER TO AS THE 196 PATENT. THIS PATENT, WHICH WAS ISSUED TO A DANISH COMPANY BY THE NAME OF FERROSAN IN 1977, DESCRIBED THE ACTIVE MOIETY IN THE DRUG THAT WE WANT TO TALK ABOUT HERE TODAY. AND WHEN I SAY ACTIVE MOIETY, I MEAN THE CHEMICAL SUBSTANCE THAT WHEN IT ENTERS THE BODY, ACTUALLY DOES THE WORK THAT IT IS SUPPOSED TO DO. AND THAT I WOULD LIKE TO REFER TO AS PAROXETINE.

NOW, THAT FIRST AND PIONEER PATENT DESCRIBED PAROXETINE AND THEN, IN SOME RATHER TECHNICAL LANGUAGE, A SALT THEREOF WITH A PHARMACEUTICALLY ACCEPTABLE ACID.

AND I DON'T WANT TO GET INTO TOO MUCH CHEMISTRY HERE, BUT THAT MEANS THAT THIS ACTIVE MATERIAL, WHICH IS A

BASE, WOULD BE MIXED TOGETHER WITH AN ACID AND A SOLVENT AND MADE INTO A CRYSTAL THAT IS CONVENIENT FOR A DRUG COMPANY TO MAKE TABLETS OUT OF.

NOW, IT'S IMPORTANT TO UNDERSTAND, FIRST, THAT F.D.A. DID NOT AND HAS NOT APPROVED THE SERIES OF PRODUCTS THAT ARE DESCRIBED IN THE 196 PATENT. IT HASN'T DONE IT. WHAT F.D.A. HAS APPROVED IS WHAT'S DEPICTED HERE IN THE FIRST BAR, PAROXETINE HYDROCHLORIDE HEMIHYDRATE, A PARTICULAR SALT OF PAROXETINE, THIS IS PAROXETINE HYDROCHLORIDE, AND THEN THIS WORD THAT FOLLOWS IT, "HEMIHYDRATE," WHICH REPRESENTS ONE-HALF MOLECULE OF WATER FOR EVERY MOLECULE OF PAROXETINE. THAT IS PRECISELY WHAT F.D.A. APPROVED WHEN IT APPROVED SMITHKLINE'S NDA IN 1992.

TODAY NO ONE IN THIS COUNTRY CAN MAKE ANY FORM OF PAROXETINE HYDROCHLORIDE. NOW, WE HAVE APPLIED FOR PERMISSION TO MARKET A PAROXETINE HYDROCHLORIDE.

NOW, THE BOTTOM TWO BARS HERE DEPICT THE TWO PATENTS THAT ISSUED IN 1999 AND THAT F.D.A. PUBLISHED IN THE ORANGE BOOK. AND THOSE PATENTS -- EACH OF THOSE PATENTS COVERS A DIFFERENT ANHYDRATE FORM OF PAROXETINE HYDROCHLORIDE.

SO RIGHT IN FRONT OF YOU WITH THE ORANGE, THE PURPLE AND THE GREEN BARS, WE HAVE THREE FORMS OF PAROXETINE HYDROCHLORIDE DESCRIBED. IF YOU READ EITHER ONE OF THE 1999 PATENTS, YOU WILL LEARN THAT ACCORDING TO SMITHKLINE, THERE

ARE AT LEAST SIX FORMS KNOWN TO SCIENCE: THE HEMIHYDRATE, FORMS A, B, C AND, D AND THEN WHAT SMITHKLINE CALLS FORM Z.

AND, SUCCINCTLY, WHAT OUR PEOPLE STARTED OUT TO DO, LONG BEFORE SMITHKLINE EVER FILED ITS APPLICATION FOR ONE OF THESE ANHYDRATE PATENTS, WAS TO MAKE FORM Z. FORM Z IS IN THE PUBLIC DOMAIN BECAUSE FORM Z WAS FULLY DESCRIBED IN THIS 723 HEMIHYDRATE PATENT, BUT NO CLAIMS WERE MADE ON THAT PARTICULAR FORM OF THE DRUG.

SO OUR POSITION IS THAT AFTER 1992, WHEN THE PIONEER PATENT EXPIRED, WE AND ANYONE ELSE IN THIS COUNTRY HAD A PERFECT RIGHT TO PRACTICE, IN EFFECT, IN EVERY AREA ON OUR TABLE THAT IS IN WHITE.

THE COURT: SAY THAT AGAIN.

MR. MOORE: IN EVERY AREA OF OUR LITTLE GRAPHIC HERE THAT IS WHITE.

THE COURT: OKAY.

MR. MOORE: NOW, THERE IS NO FACTUAL DISPUTE ON THE UNDERLYING FACTS RELATING TO THE LISTING OF THE TWO 1999 PATENTS.

SMITHKLINE TOLD THE PATENT OFFICE IN 1993 -- AND WE HAVE ATTACHED THEIR STATEMENT TO THE PATENT OFFICE -- THAT THE ACTIVE INGREDIENT IN ITS APPROVED NDA WAS PAROXETINE HYDROCHLORIDE HEMIHYDRATE, AND ON THE STRENGTH OF THAT REPRESENTATION, OBTAINED THE BENEFIT OF A TWO-YEAR EXTENSION OF ITS PATENT TERM, WHICH IT'S ENTITLED TO UNDER

OTHER PROVISIONS OF THE HATCH WAXMAN LEGISLATION BEYOND WHAT WE WANT TO TALK ABOUT TODAY.

AND LEST THERE BE ANY DOUBT ABOUT THE MATTER, SMITHKLINE TOLD F.D.A. TWICE -- NOT ONCE, BUT TWICE -- LAST YEAR WHEN IT SUBMITTED THESE NEW ANHYDRATE PATENTS FOR LISTING, THAT THE APPROVED ACTIVE INGREDIENT IN THE NDA IS PAROXETINE HYDROCHLORIDE HEMIHYDRATE.

NOW, F.D.A. THROUGHOUT HAS CLAIMED A LACK OF RESOURCES AND ABILITY TO READ PATENT CLAIMS. AND NOW IT COMES OUT THAT F.D.A. APPARENTLY CAN'T READ COVER CORRESPONDENCE DESCRIBING EXACTLY WHAT IS IN THE PATENT THAT IS BEING SUBMITTED AND EXACTLY WHAT F.D.A. HAS APPROVED.

NOW, WE DON'T HAVE ANY DISPUTE HERE TODAY ABOUT THE RELEVANT PROVISIONS OF THE FOOD, DRUG AND COSMETIC ACT EITHER. 355(B)(1) AND (C)(2) STATE THAT PATENT INFORMATION SHALL BE SUBMITTED ON ANY PATENT THAT CLAIMS THE DRUG FOR WHICH THE NDA WAS SUBMITTED.

IN OUR VIEW, THAT IS ABSOLUTELY CRYSTAL CLEAR. AND NO ONE HAS SUGGESTED THERE IS A HINT OF AMBIGUITY IN THAT STATUTORY LANGUAGE. AND WE HAVE A SUBSTANTIVE REGULATION FROM F.D.A. THAT DESCRIBES EXACTLY THE KINDS OF PATENTS THAT CAN BE LISTED. THE CATEGORY OF THREE WE'RE INTERESTED IN HERE TODAY IS THE INGREDIENT PATENT, THE ONE COVERING THE ACTIVE DRUG SUBSTANCE.

NO QUESTION ABOUT THE VALIDITY OF THAT REGULATION.

NO QUESTION THAT IT EFFECTIVELY RESTATES THE REQUIREMENTS OF THE STATUTE. NONE WHATEVER. AND THERE IS ONLY ONE WORD TRULY IN THE STATUTE THAT THE COURT MUST DEVOTE SUBSTANTIVE ATTENTION TO, AND THAT IS THE WORD "CLAIMS." AND HERE THE COURT HAS THE BENEFIT OF THE RECENT DECISION OF THE FEDERAL CIRCUIT CONSTRUING THE VERY SAME TERM IN ANOTHER PART OF THE HATCH WAXMAN LEGISLATION, DEALING WITH PATENT-TERM EXTENSION. THE WORD "CLAIM" IS CLEAR.

IF A PATENT DOES NOT CLAIM THE DRUG, THEN IT CAN'T BE LISTED. END OF STORY. WE'RE DONE. NEITHER F.D.A., NOR SMITHKLINE, DISPUTES THESE ESSENTIAL PROPOSITIONS.

NOW, I WANT TO TURN A MOMENT TO F.D.A.'S REGULATION, THE ONE WE DO QUESTION, IN WHICH F.D.A. DISCLAIMS ANY RESPONSIBILITY TO ADMINISTER (B)(1) AND (C)(2) OR THE PATENT LISTING PROVISIONS OF (B)(1) AND (C)(2). AND HERE WE HAVE A FULL ADMINISTRATIVE RECORD ON THE REASONS WHY NOT IN THE FORM OF F.D.A.'S COMMENTS AT THE TIME IT ADOPTED THESE REGULATIONS IN OCTOBER OF 1984.

F.D.A. SAYS IT CAN'T DO IT. F.D.A.'S POSITION HERE TODAY IS LET THE COURT'S DO IT. AND I SUGGEST THAT THIS DISCLAIMER OF STATUTORY RESPONSIBILITY IN FAVOR OF THE COURT'S HARDLY FITS WITH ANYTHING ELSE F.D.A. HAS TO SAY.

NOW, THE DISTRICT COURTS DEAL WITH EVERY DISPUTE WE HAVE LIKE THIS ONE, AND WITH NO ADMINISTRATIVE RECORD. NONE. IT'S A TABULA RASA FOR EVERY DISTRICT COURT WHERE

THERE IS A DISPUTE ON THE PRIORITY OF THE LISTING. AND WE BELIEVE THIS IS SIMPLY AN ILLEGAL AND, INDEED, UNCONSTITUTIONAL DELEGATION OF UNQUESTIONED STATUTORY RESPONSIBILITY ASSIGNED TO F.D.A. AND CHARGED BY CONGRESS, AND CONGRESS HAS CHARGED THE F.D.A. TO ADMINISTER IT.

THE PRINTZ CASE AND THE MORRISON VERSUS OLSON CASE WE BELIEVE ARE PARTICULARLY INSTRUCTIVE IN THAT REGARD.

AND NOW LET ME GET DOWN TO THE QUESTION OF WHY NOW. WHY ARE WE HERE NOW? WE'RE HERE NOW BECAUSE SMITHKLINE, ACCORDING TO THE ANSWER THEY FIELD TO OUR COMPLAINT, HAS ADDITIONAL APPLICATIONS FOR PATENTS PENDING IN THE PATENT OFFICE. WE LEARNED OF ONE OF THESE LAST JANUARY, MISTAKINGLY PUBLISHED BY THE P.T.O. AFTER THE APPLICATION HAD BEEN WITHDRAWN. AND SMITHKLINE TELLS US IN ITS ANSWER THAT THAT APPLICATION IS REACTIVATED AND ONGOING IN THE P.T.O.

THE TRUE DIFFICULTY HERE, BOTH FROM OUR STANDPOINT AND FROM A PUBLIC-POLICY STANDPOINT, IS THAT THIS CAN GO ON FOREVER. FOREVER. THESE 30-MONTH PERIODS CAN BE STACKED ONE ON TOP OF THE OTHER SO LONG AS THE AGENCY REFUSES TO DISCHARGE ITS STATUTORY RESPONSIBILITY.

AND THESE 30-MONTH STAYS ARE A UNIQUE STATUTORY ANIMAL. IT IS THE EXACT FUNCTIONAL EQUIVALENT OF A PRELIMINARY INJUNCTION -- EXACT -- EXCEPT THE PATENT HOLDER DOESN'T HAVE TO DEMONSTRATE PROBABILITY OF SUCCESS. THE

PATENT HOLDER DOESN'T HAVE TO DEMONSTRATE HARM. THE PATENT HOLDER DOES NOT HAVE TO EVEN POST ANY SECURITY. IT IS A FREE PRELIMINARY INJUNCTION. AND AS LONG AS THESE PATENTS CONTINUE TO ISSUE, THE PRODUCT CAN NEVER GET ON THE MARKET.

THAT, IN ESSENCE, IS THE CORE OF OUR POSITION. NOW IS APOTEX BEING HARMED TODAY? APOTEX IS BEING HARMED TODAY. THE F.D.A. VERY PROPERLY MAKES THE POINT THAT APOTEX'S PRODUCT CANNOT BE MARKETED UNTIL NOVEMBER OF 2000. THAT IS THE EARLIEST BECAUSE THAT'S WHEN THE FIRST 30-MONTH STAY WILL EXPIRE.

WELL, THESE PRODUCTS DON'T COME OFF THE SHELF --

THE COURT: THE COURT IN ILLINOIS, AS I UNDERSTAND, COULD DECIDE IT EARLIER THAN THAT.

MR. MOORE: JUDGE, I AM COUNSEL IN ILLINOIS. WE ARE AT A FACT-DISCOVERY CUTOFF POINT ON JUNE 20TH OF THIS YEAR. WE WILL PROCEED THROUGH AN ARDUOUS PERIOD OF EXPERT DISCOVERY. I EXPECT THE EARLIEST THAT CASE WILL BE TRIED WILL BE EARLY NEXT YEAR.

THE COURT: ALL RIGHT.

MR. MOORE: THE SAME IS TRUE IN PHILADELPHIA. THAT COURT IS JUST AS BUSY AS THE COURT IN ILLINOIS, AND I AM SURE JUST AS BUSY AS THIS COURT IS. WE'RE NOT GOING TO GET TO JUDGMENT IN PENNSYLVANIA IN THE NEXT MONTH OR TWO. IT'S NOT GOING TO HAPPEN. WE HAVE GOT A MOTION TO CONSOLIDATE FILED.

THE COURT: IN EITHER EVENT, WHY DOESN'T THIS LAWSUIT REPRESENT, OR CAN IT NOT BE CHARACTERIZED AS AN ATTEMPT TO DO AN END RUN AROUND THOSE TWO COURTS?

MR. MOORE: NO, YOUR HONOR. NEITHER COURT SHOULD HAVE TO DEAL WITH THE SUBJECT THAT IS BEFORE YOU. THE ISSUE OF INFRINGEMENT, WHICH WE'RE QUITE PREPARED TO GO LITIGATE IN AN APPROPRIATE FORUM -- THE ISSUE OF INFRINGEMENT IS NOT BEFORE YOU. WHAT IS BEFORE YOU IS THE SEPARATE QUESTION OF WHETHER IT IS LEGAL FOR F.D.A. TO PUBLISH THESE PATENTS AND PERMIT THIS MACHINERY OF A STATUTORY PATENT INFRINGEMENT ACTION TO GO FORWARD.

OUR PEOPLE ARE PERFECTLY PREPARED TODAY TO TAKE THE RISK THAT THEY'LL GET SUED IN A CONVENTIONAL PATENT INFRINGEMENT ACTION DOWN THE LINE. THEY ARE PREPARED TO DO THAT TODAY. WHAT THEY WANT IS THE OPPORTUNITY TO MAKE THE BUSINESS DECISION -- AND, BY THE WAY, IN THE PUBLIC INTEREST HERE, THE OPPORTUNITY TO MAKE THE BUSINESS DECISION TO GO AHEAD.

WITH RESPECT TO THE CHICAGO ACTION, IF THINGS PROCEED AS I EXPECT THEY WILL, BY THE END OF THE SUMMER WE WILL KNOW WHAT SMITHKLINE'S EVIDENCE ON THE INFRINGEMENT ISSUE IS. WE THEN HAVE THE ABILITY TO GO TO APOTEX AND SAY, "GENTLEMEN, HERE'S THE EVIDENCE. YOU CAN NOW MAKE THE BUSINESS JUDGMENT WHETHER YOU WANT TO RAMP UP AND MARKET THIS PRODUCT IN NOVEMBER," A VERY REAL POSSIBILITY.

AND, YOUR HONOR, IF YOU HAVE NO FURTHER QUESTIONS, I WOULD LIKE TO RESERVE ABOUT FIVE MINUTES FOR REBUTTAL.

THE COURT: SURE.

MR. MOORE: THANK YOU.

THE COURT: ALL RIGHT.

MR. CUTINI: MAY IT PLEASE THE COURT. I AM DRAKE CUTINI FROM THE JUSTICE DEPARTMENT ON BEHALF OF THE FEDERAL DEFENDANTS. AND WITH ME TODAY IS MS. KIM DETTELBACH FROM THE FOOD AND DRUG ADMINISTRATION.

THE COURT: ALL RIGHT.

MR. CUTINI: THIS CASE PRESENTS NO RIPE CASE OR CONTROVERSY TO THIS COURT. AS APOTEX RECOGNIZED, ITS ANDA PRODUCT CANNOT BE APPROVED PRIOR TO NOVEMBER 21ST OF THIS YEAR. AND THAT'S BECAUSE OF THE UNCHALLENGED 30-MONTH STAY -- STATUTORY 30-MONTH STAY WITH RESPECT TO SMITHKLINE'S FIRST PATENT INFRINGEMENT ACTION FILED AGAINST APOTEX.

AND WHAT IS CHALLENGING IS A SECOND 30-MONTH STAY THAT RESULTED FROM THE SECOND PATENT INFRINGEMENT ACTION FILED UP IN PENNSYLVANIA, BUT THAT SECOND 30-MONTH STAY, WHICH THEY ARE ALLEGING IS CAUSING THEIR INJURY, CANNOT POSSIBLY HAVE ANY OPERATIVE EFFECT UNTIL NOVEMBER OF THIS YEAR. FOR THAT REASON, THIS CASE IS NOT RIPE.

THERE ARE SEVERAL CONTINGENT EVENTS THAT COULD PRECLUDE THE SECOND STAY FROM EVER HAVING AN EFFECT. PRIOR TO NOVEMBER OF 2000, APOTEX MAY HAVE RESOLVED THE SECOND

PATENT LITIGATION. THEY CLAIM THAT THIS PATENT ISSUE REGARDING WHETHER THE SECOND FILED PATENT ACTUALLY CLAIMS THE FIRST PRODUCT IS ESSENTIALLY A "NO-BRAINER." IT IS SO SIMPLE THAT THE COURT CAN JUST LOOK AT THESE PATENTS AND RESOLVE THE ISSUE.

IF IT'S THAT SIMPLE, THEY COULD UNDOUBTEDLY RESOLVE THE SECOND PATENT LITIGATION UP IN PENNSYLVANIA ON A MOTION TO DISMISS, AND THAT COULD BE RESOLVED PRIOR TO NOVEMBER OF 2000, OR IT IS POSSIBLE THAT THE JUDGE HEARING THE SECOND PATENT LITIGATION IN PENNSYLVANIA COULD SHORTEN THE SECOND 30-MONTH STAY, THE ONE THAT THEY ARE ALLEGING HAS CAUSED THEIR INJURY. AGAIN, IF THE CASE IS AS SIMPLE --

THE COURT: CAN HE SHORTEN THE STAY OR MUST HE RULE ON THE MERITS? DOES HE SHORTEN IT BY RULING ON THE MERITS OR CAN HE SIMPLY SHORTEN THE STAY?

MR. CUTINI: I THINK HE CAN DO IT EITHER WAY UNDER THE STATUTE. THE STATUTE PERMITS THAT COURT TO SHORTEN THE 30-MONTH STAY WITHOUT RESOLVING THE CASE ON THE MERITS. AND, AGAIN, EITHER OF THOSE CONTINGENCIES WOULD PRECLUDE THE SECOND 30-MONTH STAY, WHICH IS WHAT THEY ARE ALLEGING HAS CAUSED THE INJURY, FROM EVER HAVING ANY OPERATIVE EFFECT AGAINST THEM BECAUSE IT CANNOT HAVE ANY EFFECT UNTIL NOVEMBER OF 2000.

FOR THAT REASON, APOTEX'S ALLEGED INJURY IS NOT FELT IN A CONCRETE WAY AND CANNOT BE FELT IN A CONCRETE WAY

PRIOR TO NOVEMBER OF THIS YEAR. THE ONLY PRESENT INJURY THEY ALLEGE IS LITIGATION EXPENSE OF THIS SECOND PATENT LITIGATION. HOWEVER, UNDER THE CASES THAT WE HAVE CITED IN OUR BRIEF, F.T.C. VERSUS STANDARD OIL AND THE MORE RECENT CASE FROM THIS CIRCUIT, PFIZER VERSUS SHALALA, SUCH LITIGATION EXPENSE CANNOT CONSTITUTE AN ARTICLE III INJURY SUFFICIENT TO INVOKE THE JURISDICTION OF THIS COURT.

APOTEX'S COMPLAINT SHOULD ALSO BE DISMISSED BECAUSE THEY HAVE FAILED TO EXHAUST -- IT HAS FAILED TO EXHAUST ITS ADMINISTRATIVE REMEDIES. F.D.A. HAS A REGULATION THAT REQUIRES THAT A REQUEST THAT F.D.A. TAKE ADMINISTRATIVE ACTION FIRST BE PRESENTED TO F.D.A.

APOTEX DID PRESENT THIS ISSUE TO THE F.D.A. IN THE FORM OF A CITIZEN'S PETITION IN FEBRUARY OF THIS YEAR. HOWEVER, THAT WAS NEARLY A YEAR AFTER THEY LEARNED OF THEIR ALLEGED INJURY, WHICH THEY SAY THEY LEARNED OF THIS INJURY IN EARLY 1999. AND THEY WERE SUED IN THE SECOND PATENT LITIGATION IN AUGUST OF 1999. SO IT WAS APPROXIMATELY SIX MONTHS OR NEARLY SIX MONTHS AFTER BEING SUED BY SMITHKLINE THAT THEY FILED THIS CITIZEN'S PETITION WITH THE F.D.A.

AND THE F.D.A.'S OWN REGULATIONS PERMIT THE F.D.A. TO TAKE 180 DAYS PRIOR TO RESPONDING TO THIS CITIZEN'S PETITION. AND THAT RESPONSE IS DUE IN AUGUST OF THIS YEAR. SO THAT TIME HASN'T EXPIRED YET.

UNDER THE PUBLIC CITIZEN CASE IN THIS CIRCUIT,

THEY HAVE PRESENTED NO -- APOTEX HAS PRESENTED NO REASON WHATSOEVER FOR ITS FAILURE TO EXHAUST, ESPECIALLY CONSIDERING THE FACT THAT THEY FIRST PRESENTED THIS ISSUE NEARLY A YEAR OR APPROXIMATELY A YEAR AFTER LEARNING OF THEIR ALLEGED INJURY. SO THE CASE SHOULD BE DISMISSED FOR THAT REASON, IN ADDITION TO NOT PRESENTING A RIPE CASE OR CONTROVERSY.

THE COURT: WHAT IS THE RELIEF THAT IS SOUGHT BY A CITIZEN'S PETITION?

MR. CUTINI: THEY CAN ASK WHATEVER THEY WANT. I BELIEVE IN THIS CASE THEY HAVE ASKED FOR ESSENTIALLY THE SAME RELIEF THAT THEY SEEK IN THIS CASE. I BELIEVE WHAT THEY ARE ASKING IS THAT THE FOOD AND DRUG ADMINISTRATION DELIST, AS THEY'RE SAYING IT -- DELIST THESE TWO PATENTS.

THE COURT: ALL RIGHT.

MR. CUTINI: THEY WEREN'T SUED ON THE 132 PATENT, BUT THEY WERE SUED ON THE 423 PATENT. SO THERE IS REALLY ONLY ONE OF THESE SUBSEQUENT PATENTS THAT IS CAUSING THEIR ALLEGED INJURY.

IF THE CASE IS NOT DISMISSED FOR RIPENESS OR EXHAUSTION AND THE COURT DOES REACH THE MERITS, THE STATUTE IN THIS CASE GIVES F.D.A. NO DISCRETION WITH REGARD TO LISTING PATENTS -- EXCUSE ME -- LISTING THE PATENT INFORMATION.

NOW, PLAINTIFF STATED TO THIS COURT THAT

EVERYTHING WAS CRYSTAL CLEAR IN THIS CASE. AND ONE THING THAT THEY DIDN'T CITE -- AND WE QUOTED THE LANGUAGE IN OUR BRIEF -- IS 21 U.S. CODE, 355(B)(1) AND 355 (C)(2), WHICH LISTS THE PATENT INFORMATION REQUIRED TO BE SUBMITTED TO THE FOOD AND DRUG ADMINISTRATION. AND THE STATUTE SAYS THAT F.D.A. SHALL PUBLISH THAT INFORMATION, IF THE COURT REACHES THE MERITS -- THIS IS A CHEVRON I CASE -- BECAUSE THE STATUTE SAYS THE F.D.A. SHALL PUBLISH THE INFORMATION. IT DOES NOT SAY THAT F.D.A. SHALL ANALYZE, AND REVIEW AND MAKE A DECISION WHETHER THIS PATENT ACTUALLY CLAIMS THIS PRODUCT. IT SAYS THAT THE F.D.A. SHALL PUBLISH THE INFORMATION.

SO THERE HAS BEEN NO DELEGATION OF ANY STATUTORY AUTHORITY BECAUSE THE F.D.A. HAS DONE EXACTLY WHAT THE STATUTE PROVIDES THAT IT SHALL DO.

THE REGULATION, AS CITED BY APOTEX, 21 C.F.R. 314.53(F) IS CONSISTENT WITH THAT. IF THERE IS A DISPUTE ABOUT PATENTS, F.D.A. ASKS THE NDA HOLDER, THE ONE THAT SUBMITTED THE PATENT, TO VERIFY THAT WHAT'S IN THE SUBMISSION IS CORRECT. AND F.D.A. RELIES UPON THAT SIGNED CERTIFICATION THAT THE INFORMATION IS CORRECT.

THE F.D.A. HAS CONSISTENTLY TAKEN THIS POSITION, BOTH IN PROPOSING ITS RULES IMPLEMENTING THE STATUTE IN 1989 AND IN IMPLEMENTING THE FINAL RULE IN 1994. IT HAS STATED CONSISTENTLY THAT ITS ROLE IS NOT TO ANALYZE AND REVIEW PATENT COVERAGE ISSUES. IT SHALL PUBLISH THE INFORMATION

PROVIDED.

NOW, THERE IS A SOLUTION TO THEIR PERCEIVED PROBLEM OF A SERIAL LISTING OF PATENTS. THE F.D.A. REQUIRES THAT THEY BE LISTED WITHIN THIRTY DAYS OF ISSUANCE OF THE PATENT. SO A COMPANY CAN'T RECEIVE A PATENT IN ONE YEAR AND THEN MANY YEARS LATER SUBMIT THAT PATENT INFORMATION. IT HAS TO BE SUBMITTED QUICKLY.

AND, IN ADDITION, THE STATUTE PROVIDES THAT THE COURT HEARING THE PATENT LITIGATION CAN SHORTEN THIS 30-MONTH STAY, WHICH IS WHAT THEY ARE ALLEGING IS CAUSING THEIR INJURY.

AND, AGAIN, IF THE ISSUES ARE AS CLEAR AS THEY PRESENT THEM, THAT SHOULDN'T BE A PROBLEM TO HAVE THAT WRAPPED UP VERY QUICKLY.

THIS CASE IS SOMEWHAT SIMILAR TO ANOTHER CASE RECENTLY FILED BY APOTEX, APOTEX VERSUS SHALALA, WHERE THEY WERE TRYING TO ARGUE THAT PRIOR PATENT LITIGATION WITH RESPECT TO TWO STRENGTHS OF A PRODUCT, 150 AND 30 MILLIGRAMS, ACTUALLY RESOLVED PATENT ISSUES AS APPLIED TO OTHER STRENGTHS -- IN THAT CASE, A 75-MILLIGRAM STRENGTH OF THE PRODUCT. AND F.D.A. SAID, "WE DON'T ANALYZE COVERAGE OF PRIOR PATENT LITIGATION." AND THIS DISTRICT COURT AGREED WITH F.D.A. FOR MANY OF THE SAME REASONS THAT WE PRESENT HERE.

THAT'S ALL I HAVE UNLESS THE COURT HAS FURTHER

SOME QUESTIONS.

THE COURT: NO. NO. THANK YOU.

ALL RIGHT, MR. MOORE.

OH, YOU ARE FROM SMITHKLINE?

MR. KUHLIK: IF I MAY, I AM BRUCE KUHLIK FROM COVINGTON & BURLING HERE ON BEHALF OF THE INTERVENOR DEFENDANTS, SMITHKLINE-BEECHAM.

THE COURT: ALL RIGHT.

MR. KUHLIK: AND WITH ME IS FORD FARABOW FROM THE FINNEGAN, HENDERSON FIRM.

IF I CAN TAKE JUST A COUPLE OF MINUTES, YOUR HONOR, WE THINK WHAT'S GOING ON HERE IS EXACTLY AN END RUN AROUND THE PATENT LITIGATION IN AN ATTEMPT BY APOTEX TO GET TWO BITES AT THIS APPLE OF THE ORANGE BOOK LISTING QUESTION.

SMITHKLINE HAS SUED THREE GENERIC DRUG APPLICANTS IN PHILADELPHIA. GENEVA, WHICH WAS SUED FIRST, LAST JULY, RAISED EXACTLY THIS ISSUE OF THE ORANGE BOOK LISTABILITY OF THIS PATENT. ZENITH HAS DONE THE SAME THING.

IN FACT, APOTEX ITSELF RAISED THIS QUESTION WITH SMITHKLINE AS LONG AGO AS LAST JULY IN WHAT'S CALLED THEIR PARAGRAPH 4 NOTICE LETTER TO SMITHKLINE, WHICH IS EXHIBIT L TO THE COMPLAINT, WHERE THEY ARE SUPPOSED TO SET OUT THE BASES FOR WHY THEY THINK THE PATENT IS INVALID OR NOT INFRINGED.

THEY ALSO POINT OUT AT PAGE 5 THAT THEY BELIEVE

THAT SMITHKLINE IMPROPERLY LISTED THIS PATENT WITH F.D.A. AND THAT THEY HAVE, AT PRESENT, BEING LAST JULY, A RIPE AND JUSTICIABLE CONTROVERSY OVER THAT QUESTION.

MOREOVER, THEY COULD OBTAIN COMPLETE RELIEF REGARDING THE LISTABILITY QUESTION. THEY COULD OBTAIN, IF THEY WERE RIGHT, IN THE CONTEXT OF THE PATENT LITIGATION, A DECLARATION ABOUT THE LISTABILITY OF THE PATENT, AN INJUNCTION DIRECTED TO SMITHKLINE, AND A STATEMENT OF WHAT THE LAW WOULD BE GOVERNING FUTURE PATENTS AS WELL.

INEXPLICABLY, THOUGH, THEY DID NOT RAISE THE ISSUE IN THE PATENT LITIGATION. INSTEAD, THEY WENT TO THE F.D.A. AND FILED A CITIZEN'S PETITION. AFTER THAT WAS PENDING FOR A LITTLE WHILE, THEY DECIDED THAT THAT WAS FUTILE AND FILED THIS CASE.

WE THINK WHAT THEY ARE DOING EXACTLY IS ASKING THIS COURT TO PROVIDE A RULING THAT WOULD BE VERY DISRUPTIVE TO THE PATENT CASE WHEN THEY COULD HAVE RAISED THE ISSUE AND GOTTEN THEIR RELIEF THERE.

WITH RESPECT TO THE MERITS, IT WOULD BE OUR ARGUMENT, YOUR HONOR, THAT THERE ARE ANY NUMBER OF REASONS WHY THE COURT WOULD NOT PROPERLY AT THIS POINT GET TO THE QUESTION OF THE ACTUAL LISTABILITY OF THESE QUESTIONS. MR. CUTINI HAS RAISED A FEW: RIPENESS AND FAILURE TO EXHAUST.

I SUGGEST THAT IF THIS COURT WERE TO REACH THE

MERITS OF THAT QUESTION, YOU WOULD HAVE TO INVALIDATE THE F.D.A. REGULATION REGARDING THE FACT THAT THE AGENCY SHALL PUBLISH THE PATENT INFORMATION SUBMITTED TO IT.

APOTEX SAYS, "WELL, THE INTERPRETATION OF THE PATENT CLAIMS IS EASY HERE." MAYBE IT IS. I DON'T KNOW. BUT IN MANY, MANY CASES, IT CAN BE VERY COMPLICATED. YOU HAVE QUESTIONS REGARDING NOT JUST THE LITERAL WORDS OF THE PATENT, BUT THE DOCTRINE OF EQUIVALENCE AND OTHER THINGS. AND IF YOU'RE GOING TO INVALIDATE THE REGULATION HERE, IT WOULD BE INVALID WITH RESPECT TO ALL OF THOSE PATENTS, AND YOU WOULD FORCE THE F.D.A. TO GET INTO EXACTLY THE ISSUES THAT CONGRESS INTENDED THEY NOT GET INTO.

BUT IF YOUR HONOR DOES REACH THE MERITS, TWO THINGS, I GUESS, I WOULD POINT OUT. FIRST, APOTEX AND F.D.A REGARD THE ACTIVE INGREDIENT HERE AS PAROXETINE HYDROCHLORIDE. THAT IS THE WHOLE BASIS FOR THE APOTEX ANDA. THEY HAVE TO SHOW THAT THEIR PRODUCT HAS EXACTLY THE SAME ACTIVE INGREDIENT, MEANING IDENTICAL UNDER F.D.A.'S REGULATIONS, TO PAXIL.

THE WAY THEY HAVE DONE THAT IN THEIR ANDA IS BY SAYING THAT THE ACTIVE INGREDIENT IS PAROXETINE HYDROCHLORIDE. AND THAT IS WHAT F.D.A. ITSELF HAS SAID IN THE ORANGE BOOK, WHICH IS THE OFFICIAL LISTING OF THESE DRUGS. AND F.D.A. HAS ALSO SAID THAT THESE HYDRATED AND ANHYDRATED ENTITIES ARE CONSIDERED TO BE THE SAME ACTIVE

INGREDIENT.

THE ONLY COURT TO HAVE ADDRESSED PRECISELY THIS ISSUE, THE ZENITH VERSUS ABBOTT CASE SAID EXACTLY THE SAME THING.

YOUR HONOR, IT APPEARS TO US THAT APOTEX IS NO LONGER EVEN TRYING TO DEPEND THEIR PRELIMINARY INJUNCTION MOTION, WHICH IS THE BASIS ON WHICH THEY GOT HERE. IF YOUR HONOR DOES BELIEVE, NOTWITHSTANDING ALL OF THOSE OTHER DEFENSES, THAT IT'S APPROPRIATE TO REACH THE MERITS OF THE PATENT LISTING ISSUE, WE WOULD REQUEST AN OPPORTUNITY TO FILE A BRIEF ON THAT.

THE COURT: ALL RIGHT. THANK YOU.

MR. KUHLIK: THANK YOU, YOUR HONOR.

THE COURT: YOU ARE HERE THIS MORNING, MR. MOORE, ON AN APPLICATION FOR A PRELIMINARY INJUNCTION. I AM NOT PREPARED TO REACH THE MERITS TODAY.

MR. MOORE: ALL RIGHT, YOUR HONOR.

THE COURT: NOW, IF YOUR PRELIMINARY INJUNCTION WERE GRANTED, WOULD THAT NOT NECESSARILY MEAN THAT I HAD REACHED THE MERITS?

MR. MOORE: YES. AND IT CAN BE DONE. THERE IS NO REASON TO DEAL WITH PROBABILITY OF SUCCESS HERE. IT'S A PURE QUESTION OF LAW. THE COURT CAN DEAL WITH IT RIGHT NOW. SHOULD I SAY RIGHT NOW? I UNDERSTAND THE NECESSITY UNDER THE RULES --

THE COURT: THIS ISN'T THE EASIEST RECORD TO UNDERSTAND, MR. MOORE. THERE IS A LOT OF PAPER HERE.

MR. MOORE: WELL, MAYBE I CAN SIMPLIFY IT A BIT, YOUR HONOR.

THE COURT: NO, I DON'T THINK YOU CAN.

MR. MOORE: WELL, I THINK WE CAN. WE BROUGHT SOME MORE DEMONSTRATIVE EXHIBITS. AND I WOULD LIKE TO LEAVE A SET WITH YOU. I WISH WE HAD HAD THEM EARLIER.

THE COURT: NO. WE'RE DEALING WITH AN APPLICATION FOR A PRELIMINARY INJUNCTION.

MR. MOORE: ALL RIGHT, YOUR HONOR. LET ME TRY TO BOIL IT DOWN AS CLOSE AS I CAN GET.

THE COURT: DEAL WITH THE TWO CRITICAL ISSUES THAT HAVE BEEN RAISED HERE AS TO WHETHER OR NOT I OUGHT TO ADDRESS IT AT ALL: FIRST, THAT IT'S NOT RIPE AND, SECOND, THAT YOU HAVE FAILED TO EXHAUST ADMINISTRATIVE REMEDIES.

MR. MOORE: YOUR HONOR, EXHAUSTION OF ADMINISTRATIVE REMEDIES GOES ONLY SO FAR, AND HERE --

THE COURT: YOU HAVE A CITIZEN'S PETITION.

MR. MOORE: WE HAVE A CITIZEN'S PETITION. WE ASKED FOR A RULING. WE CAN'T WAIT.

THE COURT: WHAT DO YOU MEAN YOU CAN'T WAIT?

MR. MOORE: F.D.A. HAS TOLD THE COURT IN ITS BRIEF VERY FRANKLY, F.D.A. IS UNLIKELY TO WITHDRAW ITS REGULATION IN WHICH IT DELEGATES RESPONSIBILITY TO A PRIVATE PARTY.

THE COURT: THAT MAY VERY WELL BE.

MR. MOORE: SO THAT'S THE BALLGAME FOR OUR MONEY. IT'S A FRUITLESS EXERCISE TO GO FURTHER WITH F.D.A.

IS THIS RIPE? WE THINK IT'S RIPE. WE THINK THE QUESTION IS ONE OF PURE LAW. WE THINK THE AGENCY ACTION ON BOTH THE LISTING OF THE PATENTS AND THE PUBLICATION IN THE ORANGE BOOK IS ABOUT AS FINAL AS IT CAN GET.

WE SEE NO REASON FOR FURTHER FACTUAL DEVELOPMENT IN TERMS OF FLESHING OUT THE DIMENSIONS OF THE ISSUE, AND WE THINK THE ANSWER IS FIT FOR DECISION NOW.

WHY DID WE COME IN HERE? ONE REASON WE CAME IN HERE WAS WHEN WE LEARNED THAT THERE IS THIS PIPELINE OF OTHER PATENTS COOKING ACROSS THE RIVER IN THE PATENT OFFICE. THERE WILL NEVER BE A TIME, ACCORDING TO F.D.A., OR SMITHKLINE -- NEVER BE A TIME WHEN IT'S RIPE. WE SAY IT IS FIT FOR DECISION. WE SAY THIS IS MORE LIKE ARTICLE III STANDING THAN RIPENESS.

THIS CASE CAN BE DECIDED NOW. IT CAN BE DECIDED, FRANKLY, DESPITE ALL THE PAPER WE HAVE GIVEN YOU, EASILY. AND IF I CAN RETURN JUST FOR A MOMENT TO THESE APPARENTLY COMPLEX ISSUES. WE HAVE GOT ONE CLAIM IN EACH OF THESE THREE PATENTS: THE HEMIHYDRATE PATENT, THE FORM A PATENT AND THE FORM C PATENT -- ONE CLAIM IN EACH OF THEM THAT THE COURT MUST READ.

AND WITHIN EACH OF THOSE CLAIMS, THERE IS ONE WORD

THAT MATTERS. IN THE HEMIHYDRATE PATENT IN CLAIM ONE, THE WORD THAT MATTERS IS "HEMIHYDRATE." IN THE TWO ANHYDRATE PATENTS, THE WORD THAT MATTERS IS "ANHYDRATE." AND WE HAVE GIVEN YOU WHAT IS AN UNDISPUTED CHEMICAL DESCRIPTION.

THE COURT: BOTH OF THOSE ISSUES ARE BEFORE, FIRST, THE COURT IN ILLINOIS AND NOW THE COURT THE PHILADELPHIA.

MR. MOORE: YOUR HONOR, WHAT'S BEFORE THOSE COURTS IS AN ISSUE OF INFRINGEMENT. THAT'S WHAT'S NOT BEFORE YOUR HONOR. WHAT'S BEFORE YOUR HONOR IS THE SEPARATE QUESTION OF WHETHER THESE PATENTS WERE LEGALLY LISTED IN THE ORANGE BOOK.

SMITHKLINE, BY ITS ON ADMISSION TO THE P.T.O., AND BY ITS OWN ADMISSION TO F.D.A., HAS SAID, "THESE ANHYDRATE PATENTS DON'T RELATE TO THE ACTIVE INGREDIENT IN OUR APPROVED NDA." END OF STORY.

THAT ISSUE IS NOT BEFORE THE ILLINOIS COURT, AND WE CONSCIOUSLY DECIDED NOT TO RAISE IT BEFORE THE PENNSYLVANIA COURT FOR THIS REASON. WE WANT TO COME TO A COURT WHERE F.D.A. IS AT THE TABLE AND THE COURT IS ABLE TO GRANT US EFFECTIVE RELIEF. THAT IS WHY WE'RE HERE, AND THAT IS WHY WE'RE NOT IN PHILADELPHIA.

NOW, THERE IS ONE ITEM OF F.D.A.'S PRESENTATION I THINK THAT NEEDS TO BE CLEARED UP. THEY TALK ABOUT SHORTENING THE 30-MONTH PERIOD. THE STATUTE ON THAT POINT

IS PERFECTLY CLEAR. THE COURT CAN LENGTHEN OR SHORTEN THE 30-MONTH PERIOD IF ONE OF THE PARTIES TO THE LITIGATION FAILS TO REASONABLY COOPERATE IN EXPEDITING THE LITIGATION. THAT IS THE ONLY STATUTORY GROUND THERE IS FOR LENGTHENING OR SHORTENING THE 30-MONTH PERIOD.

NOW, IF WE GO IN FRONT OF THE PENNSYLVANIA COURT AND WE SAY, "PLEASE SHORTEN THE 30-MONTH PERIOD BECAUSE THIS FORM A PATENT DOESN'T COVER PAXIL," WE HAVEN'T GIVEN THAT COURT A REASON TO DO ANYTHING BECAUSE THE COURT'S DISCRETION IS CONSTRAINED TO JUST THAT ONE SINGLE GROUND.

NOW, WE GET AROUND TO A FUNDAMENTAL PROBLEM BETWEEN WHAT F.D.A.'S VERY LEGITIMATE AND IMPORTANT ADMINISTRATIVE FUNCTION IS WHEN IT DEALS WITH ABBREVIATED NEW DRUG APPLICATIONS. AN ABBREVIATED NEW DRUG APPLICATION, UNDER THE STATUTE, MUST BE FOR THE, QUOTE, SAME DRUG THAT IS THE SUBJECT OF AN APPROVED NDA. THAT'S UNDER 355(J). THAT'S THE STATUTORY REQUIREMENT.

TWO YEARS AGO, THE D. C. CIRCUIT HELD, UNEQUIVOCALLY, THAT WHEN F.D.A. APPLIES THAT LANGUAGE OF "SAME DRUG," THE IMPORTANT ISSUE IS NOT WHETHER THE TWO PRODUCTS ARE CHEMICALLY IDENTICAL AT THE MOLECULAR LEVEL. THAT IS NOT THE IMPORTANT ISSUE. THE IMPORTANT ISSUE IS ARE THEY CLINICALLY IDENTICAL. AND THAT IS WHAT OUR PEOPLE WENT OUT, AT SOME SUBSTANTIAL EXPENSE, AND PROVED.

IN THE SERANO CASE, WHICH IS IN OUR BRIEF, THE D.

C. CIRCUIT HELD THAT WHERE F.D.A. DETERMINED IN THE EXERCISE OF ITS SCIENTIFIC EXPERTISE THAT DIFFERENCES IN CHEMICAL IDENTITY ARE CLINICALLY INSIGNIFICANT, THEN F.D.A. MAY TREAT THE DRUG WHICH IS THE SUBJECT OF THE ABBREVIATED APPLICATION AS THE SAME DRUG FOR PURPOSES OF 355(J).

THERE IS NO SUCH DISCRETION ON 355(B)(1) AND (C)(2), WHICH DEALS WITH AN ENTIRELY DIFFERENT TOPIC.

THERE IS MENTION OF F.T.C. VERSUS STANDARD OIL AND PFIZER VERSUS SHALALA. ONE DIFFERENCE BETWEEN OUR CASE AND PFIZER VERSUS SHALALA IS IN THE PFIZER CASE, THE CIRCUIT FOUND THAT VOLUNTARILY INCURRED LITIGATION COSTS ON THE PART OF A PATENT HOLDER DID NOT AMOUNT TO IRREPARABLE HARM. AND I CAN TELL YOU OUR CASE IS DIFFERENT BECAUSE OUR COSTS ARE NOT VOLUNTARILY INCURRED. THEY ARE FORCED ON US.

AND THERE IS ANOTHER PFIZER CASE I WOULD LIKE TO BRING UP IN RESPONSE TO THE GOVERNMENT'S ARGUMENT THAT ITS POSITION HAS ALWAYS BEEN CONSISTENT. WELL, IN FACT, IT HAS NOT. AND WE CITED ANOTHER PFIZER CASE OUT OF A DISTRICT COURT IN WHICH F.D.A. REFUSED IN 1989 TO LIST A PATENT BECAUSE THE PATENT DID NOT CLAIM THE APPROVED DRUG.

SO AT THAT POINT IN TIME, F.D.A. RECOGNIZED THE STATUTORY RESPONSIBILITY. TODAY IT DOES NOT. WE'RE ASKING THAT THE COURT INSTRUCT F.D.A. IN ITS STATUTORY RESPONSIBILITIES.

AND, FINALLY, ON THE ISSUE OF FURTHER BRIEFING,

SMITHKLINE TOLD F.D.A. IN THE CONTEXT OF THE CITIZEN'S PETITION ON FEBRUARY 29, THAT IT INTENDED TO FILE A FULLER RESPONSE SOMETIME IN THE FUTURE. IT IS NOW TWO-AND-A-HALF MONTHS LATER. NO RESPONSE HAS BEEN FORTHCOMING. SMITHKLINE HAS BEEN IN THIS CASE FOR SEVERAL WEEKS NOW, AND NO SUBSTANTIVE RESPONSE HAS BEEN FORTHCOMING. WE SEE NO REASON FOR ANY FURTHER BRIEFING.

AND, LASTLY, ON WHY NOW AND WHY NOT NINE MONTHS AGO, LET ME JUST ADD THIS. WE TRIED VERY HARD NOT TO HAVE TO COME INTO THIS COURTROOM. WE TRIED TO CONSOLIDATE THE PENNSYLVANIA CASE WITH THE ILLINOIS CASE AND GET IT ALL WRAPPED UP IN A PACKAGE. SMITHKLINE OPPOSED THE CONSOLIDATION.

THE FIST WEEK IN JANUARY, WE FINALLY OBTAINED A RULING. ABOUT THE SAME TIME, WE FIND OUT ABOUT THIS NEWLY ISSUED TABLET PATENT, OUR FIRST EVIDENCE THAT THERE IS MORE ACTIVITY OVER IN THE PATENT OFFICE. WITHIN A MONTH, WE'RE AT F.D.A. WITH OUR CITIZEN'S PETITION.

WE TRIED NOT TO BE HERE. WE TRIED NOT TO BE HERE, BUT CIRCUMSTANCES FORCED US TO COME HERE. AND I RETURN TO THE FUNDAMENTAL ISSUE -- THE MERITS ISSUES HERE, AND THEY ARE CRYSTAL CLEAR. AND NEITHER PARTY HAS COME BEFORE YOU TO CONTEST ANY ESSENTIAL ASPECT OF EITHER THE FACTS OR OUR LEGAL ARGUMENTS.

THANK YOU, YOUR HONOR.

THE COURT: ALL RIGHT. THANK YOU, MR. MOORE.

THIS MATTER IS BEFORE THE COURT ON AN APPLICATION FOR A PRELIMINARY INJUNCTION. I AM NOT SATISFIED THAT THE CASE IS CURRENTLY RIPE FOR ADJUDICATION, NOR AM I SATISFIED THAT ADMINISTRATIVE REMEDIES HAVE BEEN EXHAUSTED.

FINALLY, I DO NOT FIND THAT THE APPLICANT'S LIKELIHOOD OF PREVAILING ON THE MERITS IS SO CLEAR THAT A PRELIMINARY INJUNCTION WOULD BE WARRANTED. CONSEQUENTLY, THE APPLICATION FOR A PRELIMINARY INJUNCTION IS DENIED.

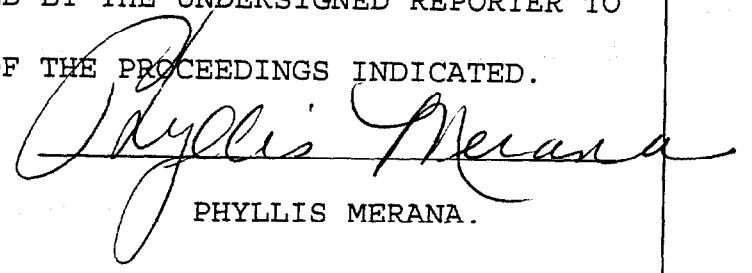
THANK YOU, COUNSEL.

MR. CUTINI: THANK YOU, YOUR HONOR.

(WHEREUPON, THE ABOVE-ENTITLED MATTER WAS ADJOURNED.)

CERTIFICATE OF REPORTER

THIS RECORD IS CERTIFIED BY THE UNDERSIGNED REPORTER TO BE THE OFFICIAL TRANSCRIPT OF THE PROCEEDINGS INDICATED.



PHYLLIS MERANA.